Mass General Brigham
Mass General Research Institute

Division of Clinical Research (DCR)

Judy Hung, MD
Director

HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

MGH Clinical Research in 2021

1/3 of all 3,000 MGPO physicians are investigators

Over 2,500 MGH staff are in clinical research support roles

Over 30 Departments, Divisions and Centers

Annual research revenue/spending over $1 billion (half of it in clinical research)

Over 2,000 active clinical trials

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RESEARCH INSTITUTE

DIVISION OF
CLINICAL RESEARCH

Division of Clinical Research Mission (DCR)

Increase quantity, quality, & efficiency
of translating science advances
into improved patient care

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Expand MGH's pool of clinical research mentors

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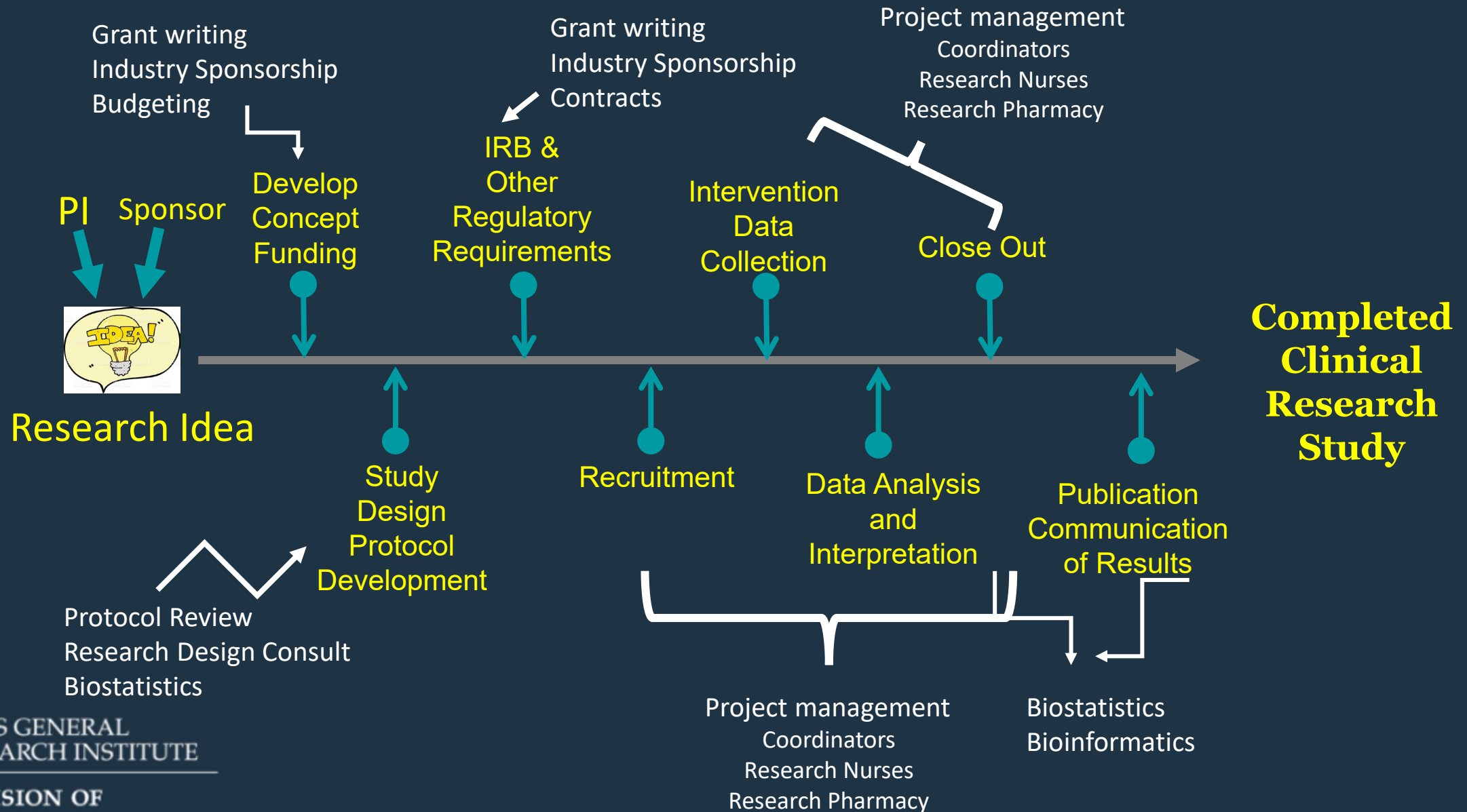Provide hands-on support to clinical investigators and study staff

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DIVISION OF
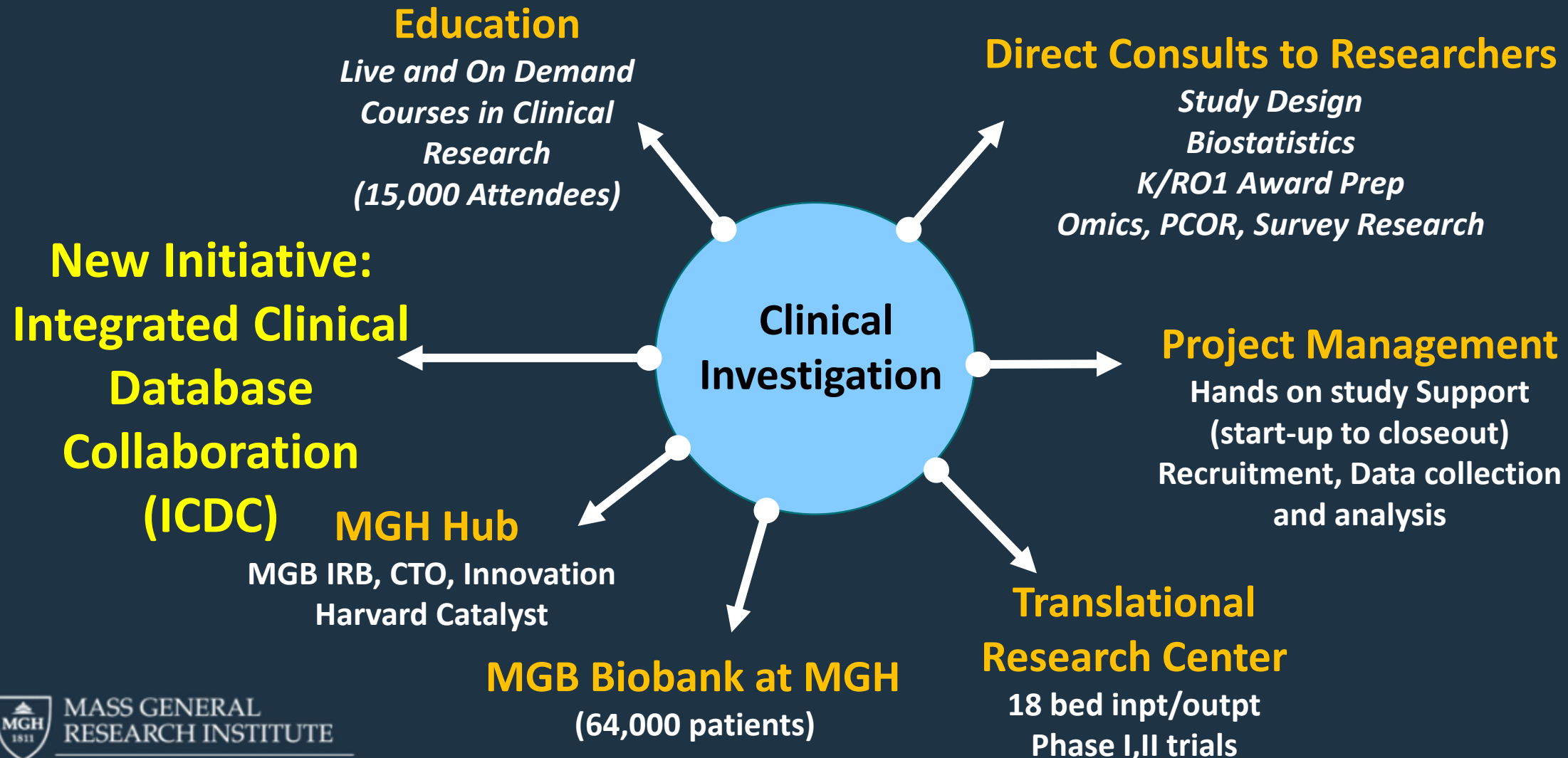CLINICAL RESEARCH

DCR: Supporting the Investigator

Grant writing
Industry Sponsorship
Budgeting

Grant writing
Industry Sponsorship
Contracts

Project management
Coordinators
Research Nurses
Research Pharmacy

PI   Sponsor

Develop Concept Funding

IRB & Other Regulatory Requirements

Intervention Data Collection

Close Out

Research Idea

Completed Clinical Research Study

Study Design Protocol Development

Recruitment

Data Analysis and Interpretation

Publication Communication of Results

Protocol Review
Research Design Consult
Biostatistics

Project management
Coordinators
Research Nurses
Research Pharmacy

Biostatistics
Bioinformatics

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Division of Clinical Research
Promoting and Supporting Clinical Research

Education
Live and On Demand Courses in Clinical Research (15,000 Attendees)

Direct Consults to Researchers
Study Design
Biostatistics
K/RO1 Award Prep
Omics, PCOR, Survey Research

New Initiative:
Integrated Clinical Database Collaboration (ICDC)

Clinical Investigation

Project Management
Hands on study Support
(start-up to closeout)
Recruitment, Data collection and analysis

MGH Hub
MGB IRB, CTO, Innovation Harvard Catalyst

MGB Biobank at MGH
(64,000 patients)

Translational Research Center
18 bed inpt/outpt
Phase I,II trials

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DCR Structure

Centers (10)	Units (12)
• Bioinformatics Consortium • Biostatistics Center • Center for Clinical Research Education • Center for Quantitative Health • Clinical Research Center • Community Access, Research and Education (CARE) • Munn Center for Nursing Research • Partners Biobank at MGH • Pediatric Translational Research Center • Translational Research Center	• Drug Discovery Rounds Unit • Global Health Research Unit • Imaging Biomarkers Unit • Mentoring Corner (K-Awards) • Omics Unit • Patient Centered Outcomes Research Unit • Philanthropy Education Unit • Qualitative and Mixed Methods Research Unit • Research Ethics Consultation Unit • Study Hypothesis and Design Unit • Survey Research Unit • Trial Innovation Unit

Tatiana Koretskaia
Director, Operations & Finance

MGH Division of Clinical Research

Consult portal: https://dcr.massgeneral.org/
Google: MGH DCR

Biostatistics Center

Mission

Engage in impactful trans-disciplinary collaborations involving quantitative methods in public health and biomedicine. This includes collaborating with MGH investigators on the development, evaluation and application of rigorous statistical and data science methods to define and address a broad range of hypothesis-driven and exploratory research questions.

At-a-glance:

- 24 faculty + 10 MS-level Biostatisticians
- + 12 additional staff (project managers, data managers, computer/admin support)
- Faculty PIs on NIH research awards; DCC for 4 large NIH projects
- Partner with DCR / DFHCC / CFAR / Catalyst (300-400 consults/year)
- Center staff and faculty currently collaborate with ~75 MGH PIs
- Free statistics consultations to K awardees
- Expanded fee-for-service operations

Andrea Foulkes, PhD.
Director of
Biostatistics Center

Request consults via
DCR site or
contact Dr. Andrea
Foulkes

afoulkes@mgh.Harva
rd.edu

Center for Clinical Research Education

Mission: To improve the quality and quantity of clinical research within MGH by providing educational opportunities for clinical investigators and study staff.

At-a-glance:

- Education Center offers more than 293 lectures (200 in 2021)and courses throughout the year
- New Learning Management System (2021)
- Hosts 22 online modules (on Healthstream)
- Streaming of live courses
- Course attendance 16,400 year to date (split evenly between PIs and Study Staff) with introduction in March of virtual format for all courses.

- To register for DCR Education Center live courses, please go to: https://learn.partners.org

Clinical Research Education Leadership

Karen Miller, MD and
Andy Nierenberg, MD, PhD

Center for Clinical Research Education

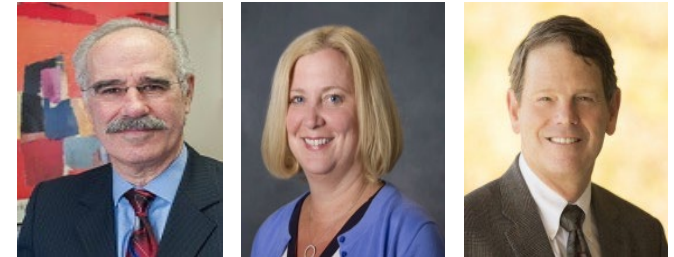**Education Program Highlights for Investigators**

- Core curriculum to prepare investigators to conduct quality research:
  - A Clinical Research Fellow's Guide to Mentoring and Resources
  - Design and Conduct of Clinical Trials
  - Good Clinical Practice in an Academic Research Institution
  - QI Bootcamp
  - Basic and Applied Biostatistics

  - Most popular elective for investigators:
  - Conquering the K: Applying for a Career Development Award
    - Clinical Research track (K23)
    - Fundamental track (K08)
    - K-awards Consultation
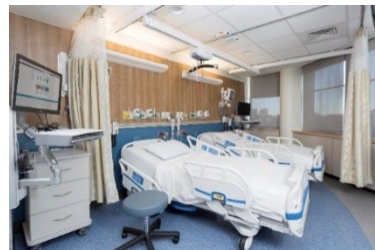   - Conquering the K-to-R Transition Course (since 2020)

Translational and Clinical Research Centers

- **18 bed Unit for human clinical research (White 12 and 13)**

- **Available to all MGH clinical investigators**

  - **Speeds the development of new drugs, devices and diagnostics with <u>industry partners</u> to improve patient care**

  - **Provides clinical research infrastructure support to <u>NIH and foundation-funded investigators</u>, as well as junior investigators and fellows**
    - **Supports > 100 PIs in all departments/ divisions**
    - **Research participants ages newborn to elderly**

CRC Director: David M. Nathan, MD
TCRC Nurse Director: Kathy Hall, RN
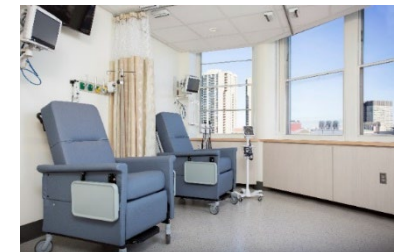TRC Director: Mason Freeman, MD

Two-bed study room

Centralized monitoring station
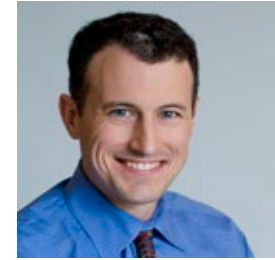

Metabolic kitchen

Infusion chairs for outpatients

Center for Quantitative Health

Mission: To facilitate investigations drawing on large clinical databases, most notably large-scale electronic health records (EHR).

Specific Services:
Consultation with investigators to plan and refine investigations making use of large clinical datasets and assistance in:

- preparation of materials describing investigations of large clinical data sets for submission to IRB or other regulatory review;
- generating descriptions of methods for incorporation in funding applications;
- generating pilot data to motivate funding applications, and for incorporation in publications;
- accessing appropriate large data sets and integration of multiple data sets – for example, use of birth and death certificate data;
- development of decision support tools which make use of results derived from large clinical data sets.

Request consults via DCR site or
contact Roy Perlis, MD
rperlis@mgh.Harvard.edu

Services of Division of Clinical Research open to all in MGB community!

Questions?

dcr.massgeneral.org