How to Provide Great Clinical Care and Provide Transitional Research

May 16, 2019

Northwell Health®

Research Related Requirements and Activities during PM&R Residency

1. **Reference Materials**:
    1. AAPMR Research Packet for Residents
    2. AAP Research Badges

2. **Elements of Research During Residency:**
    1. Monthly Didactic Critical Literature Review Course
    2. AAP Research Badges
    3. Poster Presentations/Case Reports
    4. Prospective or Retrospective Research Studies

UCI Research Badge Project for Rehab Residents: A Self Directed Guide

TABLE OF CONTENTS

Schedule of Badge Achievement

Badge # and Name	Due Date
1: Importance of Research to Physiatrists	PGY2: 12/1/17
2: Finding a Mentor	PGY2: 12/1/17
3: Intro to Concept of Level of Evidence	PGY2: 12/1/17
4: PM&R Residency Timelines	PGY2: 12/1/17
5: Protection of Human Subjects and IRB Approval	PGY2: 12/1/17
6: Literature Review & Book Chapter Writing	PGY2: 6/1/18
7: Creating Bibliographic Refs Using Software	PGY2: 6/1/18
8: RCT Quality Assessment	PGY2: 6/1/18
9: Understanding “Impact Factor”	PGY2: 6/1/18
10: Clinical Outcome Measures	PGY3: 1/1/19
11: Standard Operating Procedure	PGY3: 1/1/19
12: Confounding Variables and Bias	PGY3: 1/1/19
13: Finding Statistical Help	PGY3: 1/1/19
14: Knowledge of Research Funding	PGY3: 1/1/19

How does research relate to required residency training milestones?

LEVEL FOUR COMPETENCY (REQUIREMENTS FOR RESIDENT GRADUATION):

27. Develops and follows a learning plan that addresses gaps in knowledge establishing the foundation for life-long learning
28. Demonstrates the use of evidence-based research and tools to inform clinical decisions
33. Recognizes conflicts of interest and how they affect clinical decision-making, teaching, or research activities

LEVEL FIVE COMPETENCIES: ASPIRATIONAL / LEADERSHIP POTENTIAL

25. Stays current on the best evidence for select topics in physical medicine and rehabilitation and regularly uses evidence-based research and tools to guide clinical practice

WHY ELSE IS IT GOOD FOR ME TO ACHIEVE MY AAP RESEARCH BADGES?

AAPMR Research Workbook: A

If you do this yourself (do you want to present a poster, write a case study?), you will do this in collaboration with your mentor and in consultation with me.
This is also how we evaluate literature in our monthly didactic critical literature course

Select a researchable question
Search for related work
Justify the study
Hypotheses
Instruments and Data Sources
Preparing the research design
Developing the research protocol
Eliminating procedural bias
Identify Limitations of the Study
Data Collection Forms-NIH Common Data Elements
Reporting of Results
Statistical Analysis: Biostatistics Unit
Discussions, Interpretations and Conclusions
Administrative Arrangements: How am I going to get this done?

Resources from NIH

NIH U.S. National Library of Medicine

ClinicalTrials.gov

Fin

Home > About Studies > Learn About Clinical Studies

ABOUT STUDIES

Learn About Clinical Studies

Other Sites About Clinical Studies

Glossary of Common Site Terms

Learn About Clinical Studies

Contents

Common Research Study Types

Case Control Study	■ Compares people in a case group (those identified as having the disease) to those in a control group (those without the disease) to look at the possible causes of disease. ■ Observational and often used in retrospective "chart review" protocols ■ Demonstrates association but not cause and effect
Cohort Study	■ Tracks a group of people with shared characteristics and compares risk factors between the group that develops a disease to the group that does not develop the disease over time. ■ Observational and can be prospective (following participants as time moves forward) or retrospective (looking back at events that have already happened to participants) ■ Demonstrates association but not cause and effect
Randomized Controlled Trial (RCT)	■ Participants are randomly assigned, using a computer or matrix, into the control group or the investigational group. The control group receives the typically used or approved treatment; the investigational group receives the treatment or intervention being studied. ■ Interventional and generally considered the most rigorous study design

Study Types Continued

T2: Clinical Trials involve testing investigational products, drugs, biologics, and devices in human subjects:

- In Phase I trials, researchers test an experimental drug or treatment in a small group of people (i.e. 20-80 people) for the first time to evaluate the drug's safety, determine a safe dosage range, and identify its side effects.
- In Phase II trials, the experimental study drug or treatment is given to a larger group of people (i.e. 100-300 people) to see if the drug is effective and to further evaluate its safety.
- In Phase III trials, the experimental study drug or treatment is given to large groups of people (i.e. 1,000-3,000 people) to confirm the drug's effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.
- In Phase IV trials, post-marketing studies delineate additional information including the drug's risks, benefits, and optimal use. Phase IV trials are conducted after a drug has received FDA approval.

T3: Outcomes Research is community-based and in the "real world" setting. Outcomes Researchers may ask:

- Are new signals or trends observed for a treatment?
- How is a treatment being utilized?
- Is a treatment cost-effective?
- Are there quality indicators?

T4: Public Health and Policy Development research drives public health policy and decision-making and includes:

- Prevention trials
- Quality of life trials
- Program evaluations

How do I find out about evidence based medicine in my field and where do I direct patients for information about legitimate clinical trials?

Medline Plus: https://medlineplus.gov/?utm_source=www.domtail.com

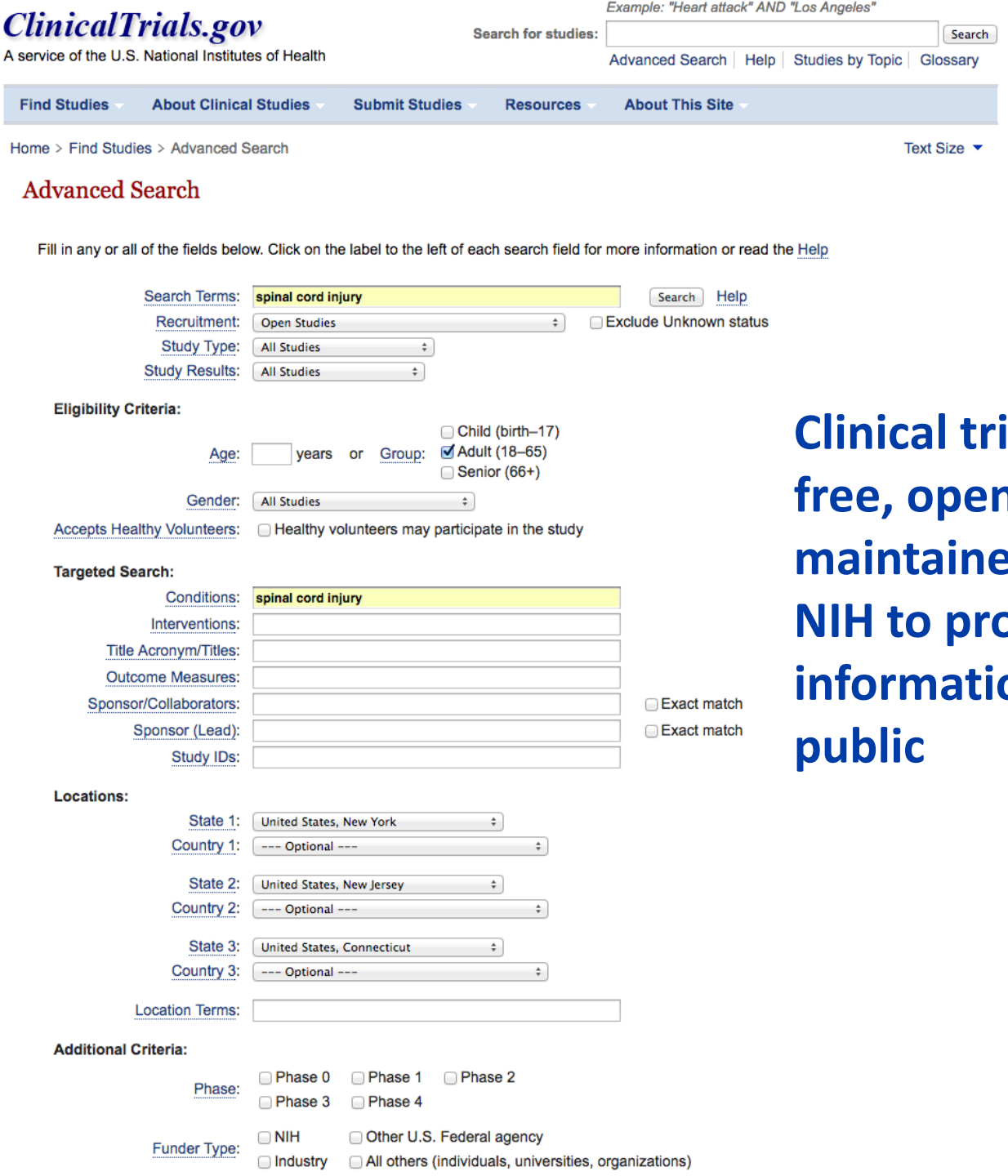
NIH Clinical Trials registry: www.clinicaltrials.gov/

Other NIH Institutes: National Institute of Neurological Disorders and Stroke (NINDS) Spinal Cord Information Page and SCI Hope Through Research:
www.ninds.nih.gov/disorders/sci/sci.htm

Professional Organizations:
AAP
AAPMR
ASIA, ASCIP, ISCOS
NARIC/NIDLRR

Medline Plus: A resource for consumers

Northwell Health



ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
Search for studies: Search
Advanced Search | Help | Studies by Topic | Glossary

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Advanced Search
Text Size

Advanced Search

Fill in any or all of the fields below. Click on the label to the left of each search field for more information or read the Help

Search Terms: spinal cord injury Search Help
Recruitment: Open Studies Exclude Unknown status
Study Type: All Studies
Study Results: All Studies

Eligibility Criteria:

Age: years or Group: Child (birth–17) Adult (18–65) Senior (66+)
Gender: All Studies
Accepts Healthy Volunteers: Healthy volunteers may participate in the study

Targeted Search:

Conditions: spinal cord injury
Interventions:
Title Acronym/Titles:
Outcome Measures:
Sponsor/Collaborators: Exact match
Sponsor (Lead): Exact match
Study IDs:

Locations:

State 1: United States, New York
Country 1: --- Optional ---
State 2: United States, New Jersey
Country 2: --- Optional ---
State 3: United States, Connecticut
Country 3: --- Optional ---
Location Terms:

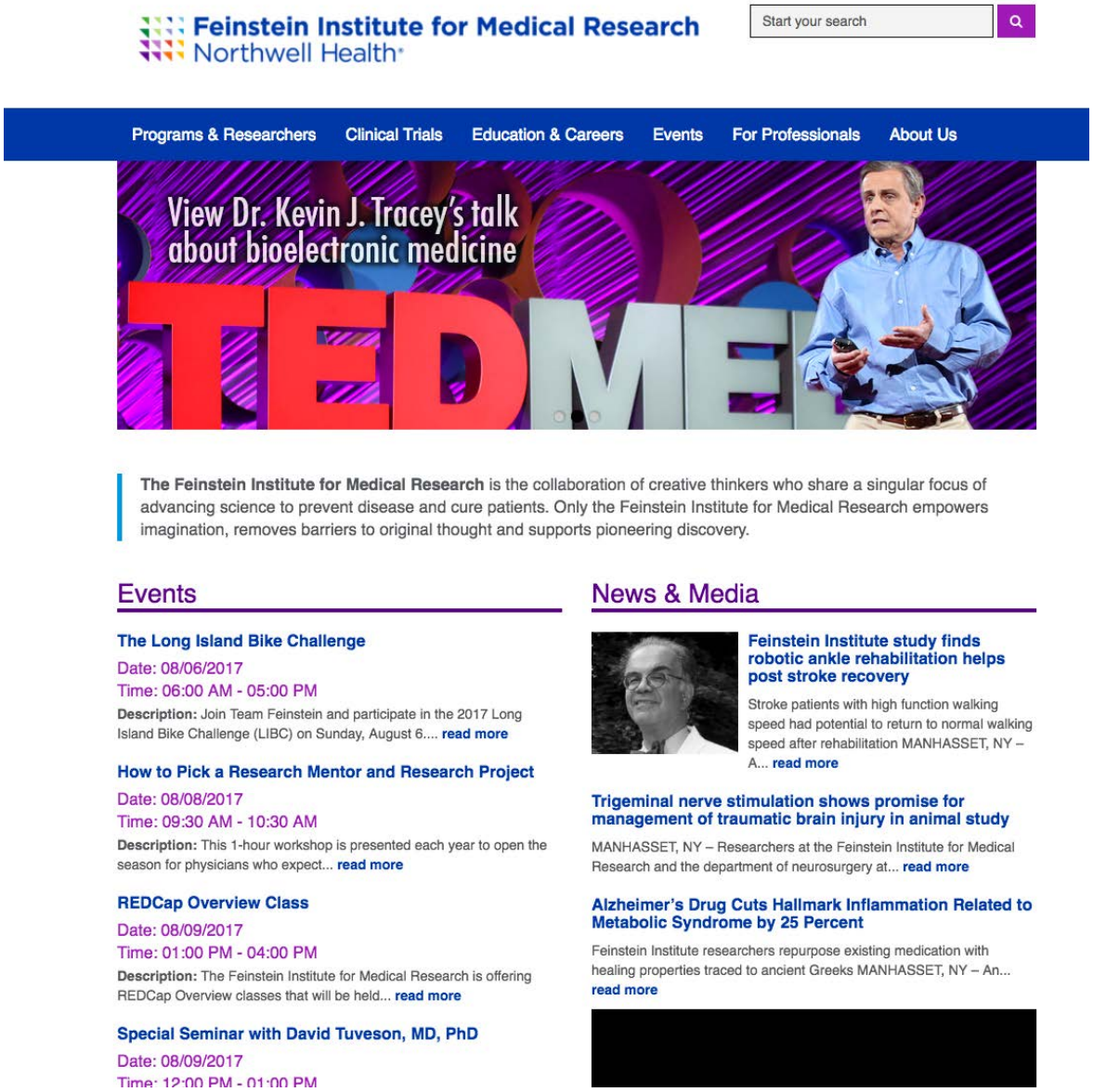
Additional Criteria:

Phase: Phase 0 Phase 1 Phase 2 Phase 3 Phase 4
Funder Type: NIH Other U.S. Federal agency Industry All others (individuals, universities, organizations)

Clinical trial.gov is free, open and maintained by the NIH to provide information to the public

What kind of research is going on within the Department and elsewhere at Northwell Health?

FIMR Overview



- >1500 scientists and researchers
- top 5th percentile of all NIH grants awarded to research centers
- PhD, MD and MD/PhD programs

FIMR

Feinstein Institute for Medical Research
Northwell Health

Start your search

Programs & Researchers | Clinical Trials | Education & Careers | Events | For Professionals | About Us

Home > Programs & Researchers

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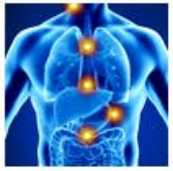
Programs & Researchers

Our Researchers

Meet our creative thinkers – the scientists and investigators at The Feinstein Institute for Medical Research.
read more

All Research Areas

Click here to learn more about all our research areas at the Feinstein Institute.
read more



Bioelectronic Medicine

Bioelectronic medicine uses nerve-stimulating technologies to regulate the molecular targets underlying a wide variety of diseases, conditions and injuries.
read more

Brain Research

Feinstein scientists conduct groundbreaking research on diseases of the nervous system for new discoveries and therapies.
read more

Genetics

Our findings in genetics and genomics are leading to new understandings of myriad diseases and human states.
read more

Health Outcomes Research

Improving patient care, population health, and quality of healthcare through a coordinated focus on scientific discovery and assessments of outcomes and delivery.
read more

Immunology & Autoimmune

Our investigators research the immune and inflammatory systems that protect us against infections and environmental hazards.
read more

Oncology & Hematology

Our scientists extensively research tumors, cancers, blood-forming organs and blood diseases.
read more


Rules


Northwell Health℠
Rehabilitation Network

AAP Badge #5: Protection of Human Subjects and IRB Approval

Complete the required Research Training (CITI program).

The health system uses the CITI online training program for researcher training. You can access the CITI webpage here: https://www.citiprogram.org. If you have not completed CITI before, create a new account, and complete the following modules:

- Basic Human Subjects Course – Biomedical Research
- Conflict of Interest Mini-Course

(Note: if you have taken the CITI training at your prior institution, you can transfer your training by re-affiliating with NS-LIJ; there may be additional questions to complete, as each institution has different training requirements.)

For additional help with CITI training, see our guidance page: www.feinsteininstitute.org/hrpp/training.

Complete your Conflict of Interest (COI) Disclosure.

Individuals responsible for the design, conduct or reporting of research are required to complete an External Interest Disclosure (COI Disclosure) electronically through eRA at least once a year or within 30 days of any new significant financial interest. To complete your disclosure, enter the eRA system here using your health

A Practical Research Handbook

A guide to conducting high quality human subject research at the North Shore-LIJ Health System:
From inception to study close-out—and everything in between.

Audience: Early career investigators including fellows, residents, students, and experienced investigators who will conduct research at the North Shore-LIJ Health System ("health system").

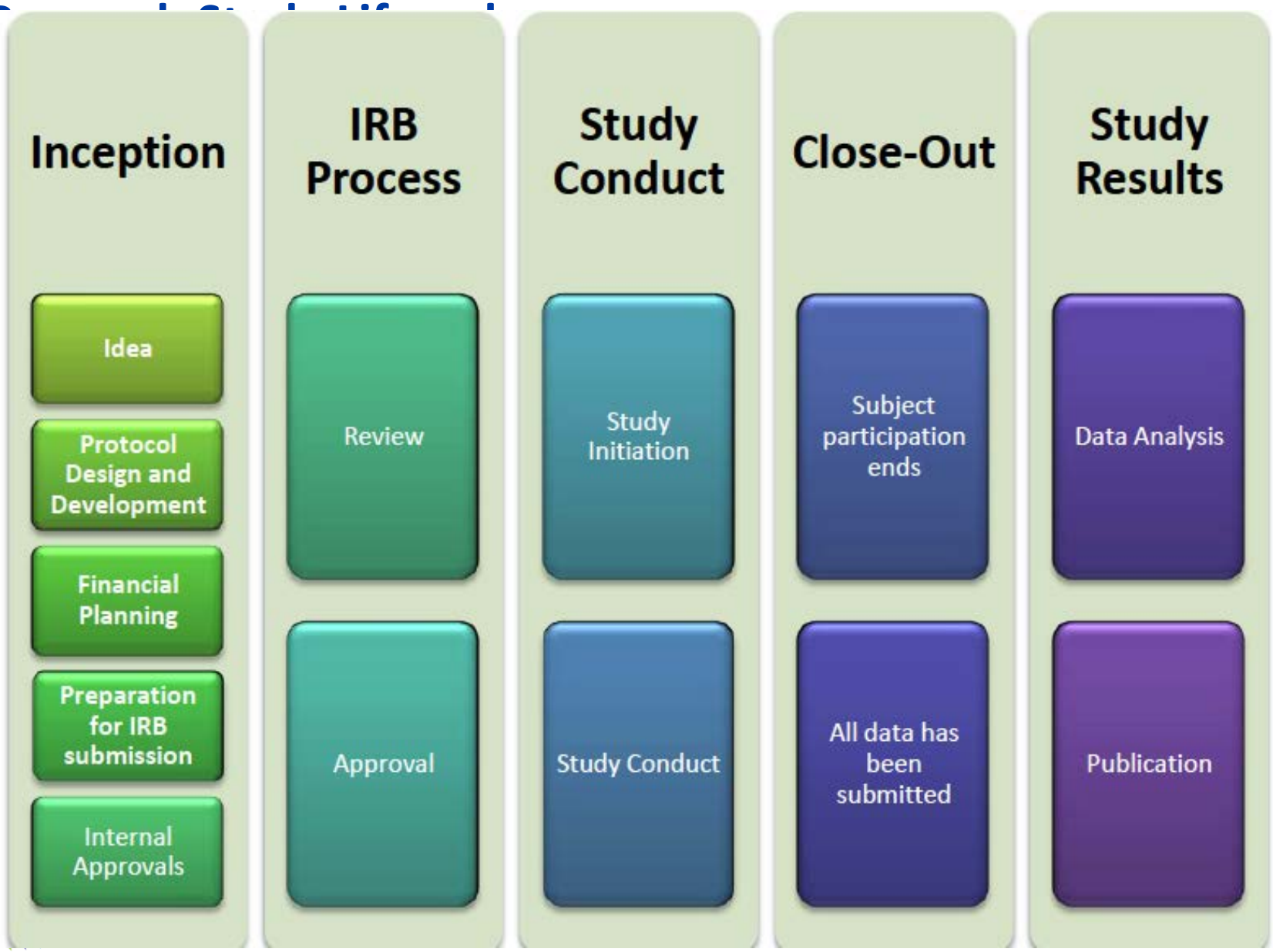
In the health system's "dashboard," this handbook falls under the missions of Teaching and Research, Quality, and Financial Performance. This guidance will enable investigators to conduct high quality, meaningful research that complies with regulations and protects subjects, resulting in new approaches that will benefit the communities that we serve and beyond.

Version 1

The Feinstein Institute for Medical Research

North Shore LIJ

NQF National Quality Forum National Quality Healthcare Award Winner 2010


Inception
Idea
Protocol Design and Development
Financial Planning
Preparation for IRB submission
Internal Approvals
IRB Process
Review
Approval
Study Conduct
Study Initiation
Study Conduct
Close-Out
Subject participation ends
All data has been submitted
Study Results
Data Analysis
Publication

Research Protocol Design, Development, Study Types

No matter what kind of study you propose to conduct at the Feinstein Institute or throughout the health system—whether your research is lab-based or clinically-based, observational or interventional, involving animals, people or assays—you should be able to:

- Develop a research study using the proper study design and methodology
- Design a study that is scientifically valid and that draws proper conclusions
- Identify and implement the appropriate phase of a study
- Conduct research with the least risk to subjects
- Identify administrative and regulatory pathways required for protocol development and success

This handbook is designed to help you meet these objectives when conducting research at the health system.

What is translational research?

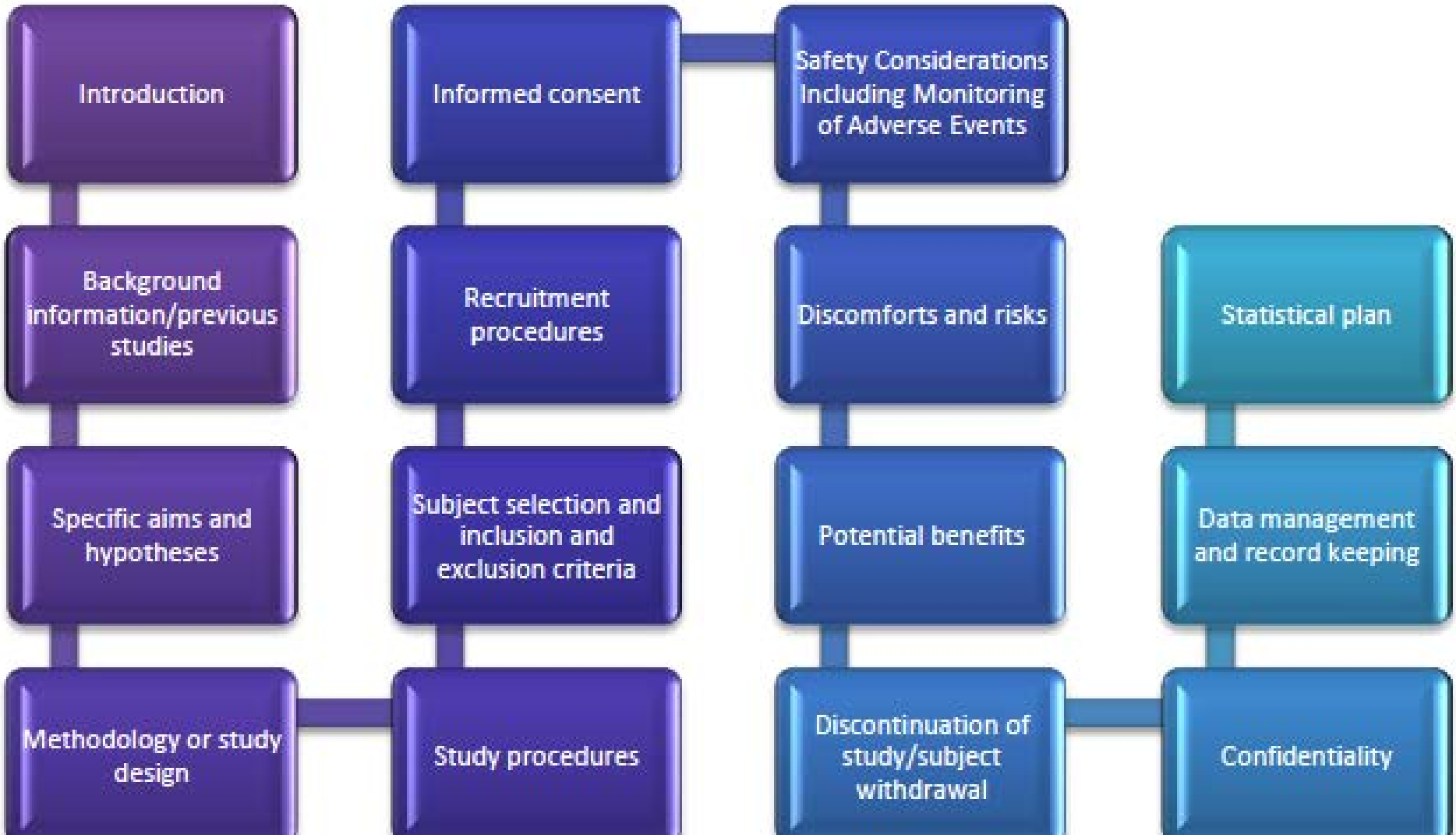
Translational Research is the ability to translate a lab discovery into community clinical care and back again in order to advance medical science. There are many steps in this process, but it can be divided into four basic phases. Researchers at The Feinstein Institute and throughout the health system are active in all four phases.

The four basic phases of translational research are:

- T1: Bench to the Bedside
- T2: Clinical Trials
- T3: Outcomes Research
- T4: Public Health and Policy Development

T1: Pre-Clinical Research, known as "Bench to the Bedside" involves:

Basic sections of your protocol should include the following:



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Quality Improvement vs. Research

Talk to your mentor and to me!

Determining what is Research and when IRB Review is Needed

- Quality Management/Quality Improvement (QM/QI) vs. Research Activities Subject to IRB Review
- Surgical Innovation vs. Research
- Compound Authorization
- What is a Case Report and when is it Research?
- Humanitarian Use Device (HUD) Guidance
- Emergency Use Guidance- New 4/3/14

Investigator Initiated Research

Design and Development

May 16, 2019

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Agenda

1. What are investigator initiated studies?
2. Types of studies
3. How are these studies performed?
   - Funding, protocol/consent/IRB
   - Other considerations
4. Sample and data collection
5. Data analysis
6. Publications
   - Abstracts, posters, and manuscripts

Disclosures

- No disclosures or conflict of interest


“We look to medical research to discover remedial measures to insure better health and more happiness for mankind”
Thomas Hunt Morgan, PhD

Why do we perform investigator initiated research?

The big advantage of going this route is that you have leeway to generate your own ideas and center your research within your own interests and expertise.

Staying grounded in what you know best is a critical ingredient of success, especially if you are a relatively new investigator with an unknown track record.

Though you have the most latitude to generate your own ideas, you will have to convince peer reviewers that your topic can make an impact worthy of investment.

What types of studies can be performed?

- Pre-clinical and clinical studies
- Observational studies; e.g., epidemiological studies or outcome studies
- Other research; e.g., disease states, diagnostics, medical devices, screening tools, and surveys

How do we perform these studies?

Feasibility

- Costs
  - Obtaining funding
    - Institutional
    - Governmental
    - Other 3rd party organizations
  - Establishing a budget

- Staffing
    - Other clinicians
    - Research RNs
    - Clinical Research Coordinators
    - Interns/Assistants
  - Data/sample collection, analysis and storage
  - Statisticians (Bioinformatics)

How do we perform these studies?

Protocol & Consent Development

- Background information and previous studies
- What “new” idea/hypothesis are you investigating?
- Inclusion/Exclusion criteria
  - Who will be included in your subject population?
  - How many patients do you expect to recruit?
    - What amount would make statistical significance? (Speak with statistics)
  - Do you have access to enough patients?
- Risk/Benefit analysis
  - Will your patient population be willing to participate?
  - Greater than minimal risk study – how will you justify the risks?
- Consent documentation
  - Language of the consent is important
  - Revised Common Rule

Institutional Review Board (IRB)

An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

Concentration on HIPAA and protection of patients.

- What data will be collected?
- Where will it be stored?
- How will samples be labeled?

Northwell IRB

- On-line submissions
- Offer templates for protocol and consent documents
- IRB staff assigned per department
  - Helpful in editing and refining protocol to meet institutional standards
  - Roles (e.g., principal investigator, research coordinator, etc) and responsibilities defined (who will obtain consent? who has access to data?)

Funding secured, research staff in place and IRB approved…now what?

- Inform staff and review protocol. Allow for staff to raise questions/concerns.

- Finalize logistics
  - Sample storage and transportation
  - Placement and inventory of necessary supplies

- Begin recruitment and sample/data collection
  - Identification of recruited patients and tracking for follow up visits
    - Allscripts EMR is capable of “flagging” patients to inform your office as well as other clinicians the patient sees of his or her participation in a clinical research study.

Sample & Data Collection

Biologic Samples

- Correct container with appropriated preservative
  - Pre-storage preparation (e.g., centrifugation)
  - Remove identifying information from all labeling
- FIMR Biorepository
  - Resource to store and process samples
  - Ease of access if collaborating with FIMR lab

Electronic Data Capture

- REDCap Database
  - Secure, NIH/IRB approved data entry system
    - Hosted on Northwell Health server
    - Secure, password protected access
    - All data entry is logged
  - Customizable entry forms
    - Calculations, uploads, questionnaires
  - Statistical data is easily obtained
  - Northwell Bioinformatics team
    - Can be hired to develop and maintain database
    - Offer classes to teach beginner & intermediate REDCap skills

What are you discovering?

Statistical Analysis

- Maintain contact with statistician. Ensure that any changes made do not void data before making them
- Analysis of data may change focus of the study
- Advanced statistics are required for study to have power and impact

Tell everyone what you found!

Publishing results

- Manuscript development
  - Writing manuscripts are often tedious and labor intensive
  - Can have manuscripts developed by 3rd party consultants for a fee
  - Research potential publications that you intend to submit to
    - What types of research studies do they typically publish?
    - What format do they require the abstract and/or date to be in?
    - Who will review the study?

- Poster presentations
  - A way to quickly announce results before development of a manuscript

Thank You