Introduction to the Principles and Practice of Clinical Research 2013 - 2014

Course Co-Directors
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Frederick P. Ognibene, M.D., Deputy Director, Educational Affairs & Strategic Partnerships, CC
Laura Lee Johnson, Ph.D., Statistician, NCCAM

October 21, 2013

President Harry S. Truman at NIH Clinical Center Dedication - 1952
**NIH Clinical Center**

- **Opened:** July 6, 1953
  - 1st patient: Charles C. Meredith, MD, farmer with prostate cancer
  - 18 patients admitted that day:
    - Cancer
    - Heart disease
    - Arthritis
- **Delayed Opening:**
  - caused by "...Budget Bureau's refusal to provide operating funds..."
- **Construction Cost:** $64M
  (*$850M in today's dollars*)

*BRDPI inflation data

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**Informed Consent at the NIH Clinical Center**

Report submitted to Medical Board by Clinical Research Committee addressed "how to provide each patient with a reasonable understanding of his role in a study project and the means for obtaining evidence of such understanding and consent."

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**Selected CC Accomplishments**

**First 50 Years**

- 1st formal review of clinical protocols, model for IRBs
- Creation of the normal volunteer program
- Chemotherapy for cancer
- Use of blood lipid levels as biomarkers of cardiovascular disease
- Use of leptin to treat lipodystrophy
- 1st use of nitroglycerin for heart attack
- Enzyme replacement therapy for Gaucher’s Disease leading to founding of the Genzyme Corporation
- 1st successful artificial mitral heart valve
- Immunosuppressive therapy for nonmalignant diseases
- 1st fluoride gels to treat dental caries as an infectious disease
Selected CC Accomplishments
First 50 Years (continued)

• 1st electronic medical information system (MIS) for clinical research
• 1st treatments of AIDS (AZT, ddl, ddC)
• Blood tests for AIDS, hepatitis
• Acyclovir for genital herpes
• 1st gene therapy (ADA Deficiency)
• Lithium for treatment of depression
• Recognition and treatment of pediatric obsessive-compulsive disorder

Selected CC Accomplishments
Last Decade

• Immunosuppressive therapy for aplastic anemia
• Discovery of autoinflammatory diseases
• Identification of genes for stuttering
• Cell therapy for metastatic melanoma
• 1st immunotoxin to treat malignancy (hairy cell leukemia)
• Identification of the genetic basis of kidney cancer with novel therapeutics
• New approaches for diagnosis and management of prostate cancer
• Application of microbial whole genome sequencing in hospital epidemiology

Clinical Center Profile

• >480,000 patients since opening in 1953
• 240 beds; FY 2013 Budget $397.6M
• Hospital surrounded by research labs
• Every patient is on a research protocol
• Care is free
• Patient travel/housing provided as needed
• 2,800 CC employees + ~4,000 employees from 17 ICs that use hospital
• 1,255 credentialed physicians
• 1,530 active protocols
  • Interventional/Clinical Trials - 730 (47%)
  • Natural History - 715 (47%)
  • Screening - 66 (4%)
  • Training - 26 (2%)
**Mission**

Science

Patient Care/
Safety

**Training**

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2013-2014 IPPCR Enrollment Data*

Enrolled at the NIH 433

Enrolled at 43 remote locations 1,271

Total enrollees (as of 10/21/13) 1,704

*10/21/2013

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**IPPCR**

43 Participating Off-Campus Sites

<table>
<thead>
<tr>
<th>U.S.</th>
<th>California</th>
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<tbody>
<tr>
<td>Armona Institute for Medical Research, Inc.</td>
<td>Michigan State University Department of Psychiatry</td>
</tr>
<tr>
<td>Beth Israel Deacunno Medical Center, Center for Resuscitation Science &amp; the Cardiac Arrest Center</td>
<td>Biomedicine School of Medicine</td>
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<tr>
<td>Children's National Medical Center</td>
<td>National Institute of Environmental Health Sciences</td>
</tr>
<tr>
<td>Harbor-UCLA Medical Center</td>
<td>Rutgers, The State University of New Jersey</td>
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<tr>
<td>H. Lee Moffitt Cancer Center</td>
<td>Salus University</td>
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<tr>
<td>LA Biomed/ Harbor UCLA Medical Center</td>
<td>Sinai Hospital of Baltimore</td>
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<tr>
<td>Loma Linda University Department of Medicine</td>
<td>Texas Back Institute Clinical Research, LLC, Plano, TX</td>
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<tr>
<td>Medstar - Columbia</td>
<td>UCLA K30 Program</td>
</tr>
<tr>
<td>Michigan State University Department of Psychiatry</td>
<td>University of Arizona</td>
</tr>
<tr>
<td>Biomedicine School of Medicine</td>
<td>University of South Florida College of Medicine</td>
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<tr>
<td>U.S.</td>
<td>International</td>
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<tr>
<td>University of Utah</td>
<td>Affiliated Union Hosp, Tongji Med Coll</td>
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<tr>
<td>University of Wisconsin-Madison</td>
<td>Huazhong Univ of Science and Tech, Wuhan, China</td>
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<tr>
<td>Veteran's Affairs Medical Center – Vermont</td>
<td>AFRIC Sante – Bobo-Dioulasso, Burkina Faso</td>
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<tr>
<td>Walter Reed Army Medical Center</td>
<td>Alianza Mexicana de Centros de Investigacion Clinica (AMEXICA), Monterrey, Mexico</td>
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<tr>
<td>Washington DC Veteran's Administration Medical Center</td>
<td>The Australian National University, John Curtin School of Medical Research, Canberra, Australia</td>
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<td>Cairo University, Kasr Al Aminy School of Oncology (KASO) – Cairo, Egypt</td>
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<td>Centre de Documentation et d’Information sur le Medecament (CEDIM) – Ouagadougou, Burkina Faso</td>
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<td>Dow University of Health Science – Karachi, Pakistan</td>
<td>Universitiy of Ghana School of Public Health - Accra, Ghana</td>
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<tr>
<td>Grupo Oncology Cooperativo</td>
<td>University of Puerto Rico, Puerto Rico Clinical and Translational Research Consortium – San Juan, Puerto Rico</td>
</tr>
<tr>
<td>Chili de Investigation Chileno</td>
<td>Universidad Central del Caribe Collaborative Research Center – Bayamon, Puerto Rico</td>
</tr>
<tr>
<td>Cooperative Group for Oncologic Research (GOCCHI) – Santiago, Chile</td>
<td>Universidad Estadual Paulista (UNESP) Botucatu Medical School – Sao Paulo, Brazil</td>
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<tr>
<td>Hospital de Cancer de Barretos – Sao Paulo, Brazil</td>
<td>Universidad de La Salle, Caracas, Venezuela</td>
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<tr>
<td>Hospital Angeles Clinical Londres – Mexico City, Mexico</td>
<td>Centro de Investigacion en Cancerologia (CIC) – Mexico City, Mexico</td>
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NIH Curriculum in Clinical Research

Introduction to the Principles & Practice of Clinical Research
15,741 participants since course introduced in 1995

Principles of Clinical Pharmacology
9,654 participants since course began in 1998

Ethical and Regulatory Aspects of Human Subjects Research
5,503 participants since course began in 1999

http://clinicalcenter.nih.gov/training/index.html

October 2013

IPPCR Administrative Pointers

• Course Textbook
  • Principles and Practice of Clinical Research, Third Edition
  • Available at NIH FAES Bookstore, Bldg 10, Room B1L101 or on-line

• Handouts posted on course website:
  http://www.cc.nih.gov/training/training/ippcr/info.html

• Lecture evaluations: link will appear on the course website following the lecture

Since 1995, Over 30,000 students world-wide have participated in the NIH Curriculum in Clinical Research.

http://www.cc.nih.gov/training/training/ippcr/info.html
IPPCR Administrative Comments

Video Archive
• video of each lecture will be posted within 48hrs following presentation

Questions
• should be sent to the course mailbox and answers posted on course website od_ippcr@mail.cc.nih.gov

Exam/Certificates
• at completion of course, examination will be posted on the course website
• certificates - final exam grade of 75% or higher

Questions regarding course: (301) 496-9425

Introduction to the Principles & Practice of Clinical Research

Module  I – Study Design and Statistics
• Overview of clinical study design
• Design of epidemiologic studies
• Efficient clinical trials
• Study participant selection
• Measures
• Using large datasets for population-based health research
Module II – Ethical, Legal, and Regulatory Considerations
- Ethical principles in clinical research
- Legal issues
- Research with vulnerable participants
- Mock IRBs
- Inclusion of women and minorities in clinical trials

Module III – Preparing and Monitoring Clinical Trials
- Information resources for clinical research
- Protocol development
- Evaluation of a protocol budget
- NIH peer review process
- Pharmaceutical development: management of projects

Module IV – Miscellaneous Topics
- Scientific conduct
- The clinical researcher and the media
- Technology transfer
- Health disparities research
- Dissemination and implementation research
Introduction to the Principles & Practice of Clinical Research

Special Lecture

Clinical Research from a Patient’s Perspective

Jerry Sachs