Intramural-Extramural Collaboration at the NIH Clinical Center

- Brief History of the NIH Clinical Center
- Unique Resources
- Current Challenges
- Two New Programs
- Your Feedback
A Brief History

• **Important Dates**
  
  • 1953: Warren Grant Magnuson Clinical Center Opens
  
  • 2005: Expansion - “Mark O. Hatfield Clinical Research Center”
  
  • 2011: Clinical Center receives the Lasker-Bloomberg Public Service Award
A Brief History

• **Size and Scope**
  • 870,000-sq ft
  • 240 inpatient beds
  • 82 day-hospital stations
  • 1,500 clinical research studies currently in progress
  • Over 400,000 clinical research participants since opening
  • 1,200 credentialed physicians, dentists, and PhD researchers
  • 620 nurses and 450 allied health-care personnel
Medical Research Milestones

- development of chemotherapy for cancer;
- the first use of an effective immunotoxin to treat a malignancy (hairy cell leukemia);
- the first gene therapy; the first treatment of AIDS (with AZT);
- development of tests to detect AIDS/HIV and hepatitis viruses in blood, which led to a safer blood supply.
A Unique Resource

- Wholly dedicated to research
- Highly flexible facility allowing more/less inpatient beds or day-hospital stations
- On site lodging
  - The Children’s Inn: Pediatric patients and their families
  - Edmond J. Safra Family Lodge: 34 rooms for families of adult CC patients staying in intensive care.
• Patient Cohorts
  • Healthy Volunteer Cohorts
  • More Than 400 Rare Disease Cohorts, For Numerous Genetic Disorders
  • Undiagnosed Diseases Program
  • Patients from all 50 states and from around the world.
  • 10,000 new research participants yearly (patient volunteers and healthy volunteers)
A Unique Resource

• Extensive Training
  • Focus on clinician-scientists.
  • Clinical Research Curriculum
  • Clinical/Research Electives for Students, Residents, and Clinical Fellows
  • A Sabbatical in Clinical Research Management
  • Use of the NIH Clinical Center by Extramural Investigators for Collaborative Partnerships
  • NIH Lasker Clinical Research Scholars Program
NCI CCR Resources at the NIH Clinical Center

- Molecular Imaging Clinic
  - Access to cyclotron for production of novel agents imaging agents
  - Access to whole body MRI-PET scanner

- NIH Center for Interventional Oncology (Wood Adjunct Appt in CCR)

- Clinical Molecular Profiling Core
  - Standardized biospecimen collection
  - MicroRNA profiling of tumor/normal
  - Genetic background profiling of patient
  - Biomarker development to monitor targeted therapies
Molecular Imaging Clinic

Active Human Protocols:

- $^{18}$F-FLT: DNA Proliferation
- $^{18}$F-Fluciclitide: Integrin-angiogenesis
- $^{18}$F-Paclitaxel: Drug Delivery
- $^{18}$F-FES: Estadiol Imaging
- $^{18}$F-ACBC: Amino acid transport
- $^{18}$F-Sodium Fluoride: Bone Metastases
- $^{11}$C-Acetate: Fatty acid metabolism
- $^{111}$In-Trastuzumab: HER2 imaging
- $^{111}$In-MorAb009: Anti-Mesothelin
NIH Center for Interventional Oncology

- Offers new and expanded opportunities to investigate cancer therapies that use imaging technology to diagnose and treat localized cancers in ways that are precisely targeted and minimally or non-invasive
  - Cutting edge technology
    - MRI, PET, CT
- Ideally and uniquely positioned to provide an interdisciplinary environment combining training, patient treatment, translational research and development in interventional oncology

Brad Wood
Clinical Molecular Profiling Core

All CCR Clinical Protocols

Tissue Procurement and Processing Facility
LCM, Annotation

Intensive Clinical Characterization

Profiling  Sequencing  Tissue Proteomics  Experimental Imaging  Pharmacy-genomics
Current Challenges

• Increasing costs, deceasing budgets

• Need to better serve the extramural community as a locus for collaborative work.

• Better utilization as a training ground for clinical researchers.

• NIH-wide under-utilization of inpatient beds (69% in FY 10, 68% in FY 11)
  • NCI averages 85% utilization
  • NCI uses 38% of all inpatient days
Current Challenges

• A Congressionally-mandated Scientific Management Review Board (SMRB) Established

• Recommendations:
  • NIH Clinical Center “should… serve as a state-of-the-art national resource, with resources optimally managed to enable both internal and external investigator use.”
  • Funding model should ensure that when the CC inflationary increase exceeds the annual increase in the NIH budget, NIH should support, not only IRP
  • Consistent with CC becoming a resource available to extramural community
  • Recognized that potential funding is very small in relation to total NIH budget
Two New Approaches To Intramural-Extramural Collaboration

• Use of the NIH Clinical Center by Extramural Investigators for Collaborative Partnerships

• NIH Lasker Clinical Research Scholars Program
Proposed Program Structure

- **Request for Information (RFI)**
  - Release Date: October 12, 2011
  - Response Date: December 1, 2011
- **RFP planned based on RFI responses**
Use of the NIH Clinical Center by Extramural Investigators

• A “Bench to Bedside” program
• Cooperative agreements between basic and clinical researchers, both within and outside the NIH-U01 mechanism
• Use of the CC for extramural-intramural collaboration
• Teams will have at least one NIH intramural and one extramural investigator.
• Access to the NIH Clinical Center resources
• **Are these programs:**
  • Meeting a need?
  • Likely to attract top candidates?
  • Structured correctly?
  • What are the possible pitfalls?
  • How can we make them better?
Use of the NIH Clinical Center by Extramural Investigators for Collaborative Partnerships

- Would this program be well-received as proposed?
- Likely to attract top researchers?
- Structured correctly?
- What are the possible pitfalls?
- How can we make it better?
Two New Approaches To Intramural-Extramural Collaboration

- Use of the NIH Clinical Center by Extramural Investigators for Collaborative Partnerships

- NIH Lasker Clinical Research Scholars Program
NIH Lasker Clinical Research Scholars Program

• To support research during the early stage careers of independent clinical researchers.

• Intended to be a unique bridge between the NIH intramural and extramural research communities
NIH Lasker Clinical Research Scholars Program

• Two phases

• Phase One: 5-7 year appointment as an NIH intramural tenure-track investigator with independent research budget

• Phase Two: Successful scholars
  • Apply for up to 5 years of NIH support ($500,000/yr) for their research at an extramural research facility or
  • Apply for a tenured position at NIH to remain as an investigator within the intramural program.
Program Candidates:

- Translational/clinical researchers after fellowship training
- Competitive for tenure-track positions at the NIH
- Ability to do independent research
Program Partners:

1. Lasker Foundation
   • Participation of Lasker Laureates in selection and mentoring;
   • Financial support for 2011 launch
   • Travel and lodging for incoming Scholars to attend Lasker Awards ceremony
   • Annual Scholars and mentors meeting.
   • Scholars will be highlighted on Lasker website, reports and publications, as appropriate.
Program Partners:

2. **Intramural NIH Support**
   - IC financial support for up to 7 years of salary and research operating budget.

3. **Extramural NIH Support**
   - IC-based financial support for 4 years of independent support (salary and/or research operating budget).
Competitive Merit-based Reviews

• **Initial Review**: Extramural Review Committee through CSR;

• **Interim Review(s)**: NIH Boards of Scientific Counselors made up of outside expert reviewers (every 2-4 years);

• **Final Review on Transition at 5-7 years**: Extramural Review Committee or Central Tenure Committee process.
FY2011 Applicant Summary

15 Eligible applicants:

- 1 Neuroradiology
- 2 Hematology/oncology
- 2 pediatrics/medical genetics
- 1 pediatric neurology
- 3 psychiatry
- 2 infectious disease
- 1 endocrinology
- 1 oncology
- 2 cardiology
FY2011 Review Process

- Peer reviewed (July 2011)
- Evaluation by Intramural Scientific Directors and Clinical Directors
- On-campus interviews (August - October, 2011)
- Two candidates currently under consideration
FY2012 Program

- Application deadline is January 24, 2012

- Application decreased from 12 to 6 pages

- Applicants will address how their proposed research will utilize the IRP environment

- Applicants must be within 10 years of completing their core residency (up from 6 years)
NIH Lasker Clinical Research Scholars Program

- How do we attract a more robust pool of oncology applicants?
- Structured correctly?
- How can we make it better?