



# National Cancer Advisory Board December 2011

*Center for Cancer Research*  
*Lee J. Helman, M.D.*

# Intramural-Extramural Collaboration at the NIH Clinical Center

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- **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



## A Brief History

- **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.



## A Unique Resource

- **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

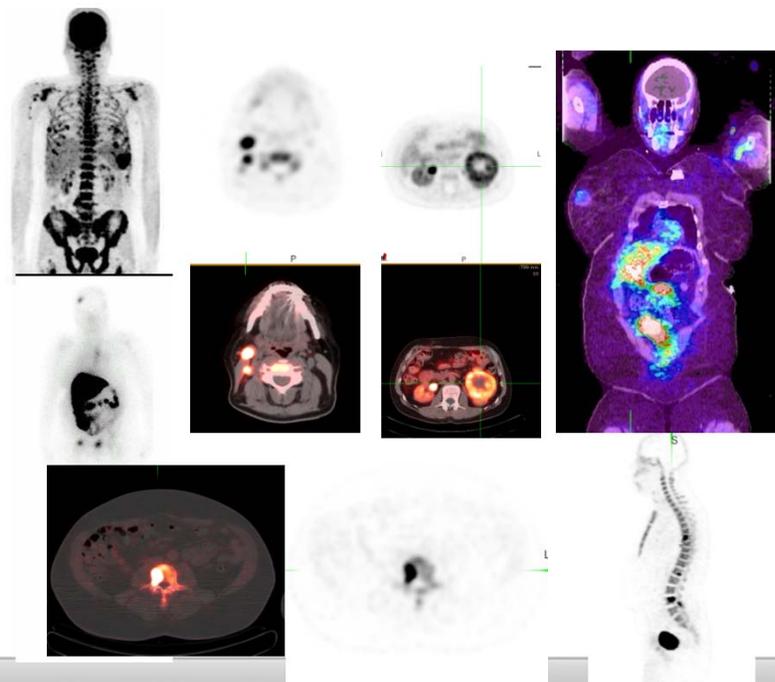


# Molecular Imaging Clinic



## Active Human Protocols:

- <sup>18</sup>F-FLT: DNA Proliferation
- <sup>18</sup>F-Fcytidine DNA Proliferation
- <sup>18</sup>F-Fluciclitide Integrin-angiogenesis
- <sup>18</sup>F-Paclitaxel Drug Delivery
- <sup>18</sup>F-FES Estadiol Imaging
- <sup>18</sup>F-ACBC Amino acid transport
- <sup>18</sup>F-Sodium Fluoride Bone Metastases
- <sup>11</sup>C-Acetate Fatty acid metabolism
- <sup>111</sup>In-Trastuzumab HER2 imaging
- <sup>111</sup>In-MorAb009 Anti-Mesothelin



# NIH Center for Interventional Oncology



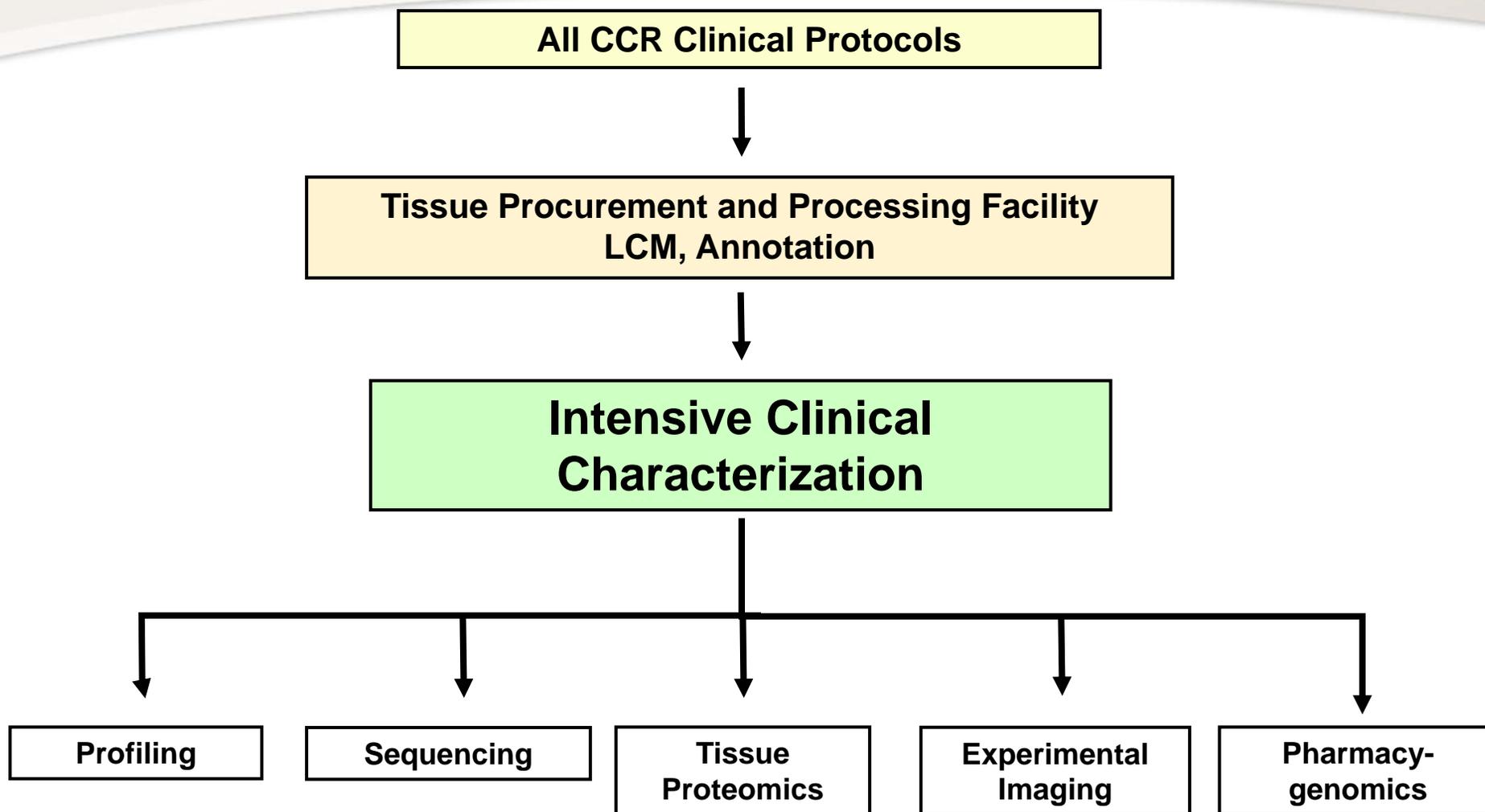
- Offers new and expanded opportunities to investigate cancer therapies that use imaging technology to diagnose and treat localized cancers in ways that are precisely targeted and minimally or non-invasive
  - Cutting edge technology
    - MRI, PET, CT
- Ideally and uniquely positioned to provide an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

Brad Wood

<http://www.cc.nih.gov/centerio/index.html>



# Clinical Molecular Profiling Core





## Current Challenges

- **Increasing costs, decreasing 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**



## Your Input

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- **Are these programs:**
  - Meeting a need?
  - Likely to attract top candidates?
  - Structured correctly?
  - What are the possible pitfalls?
  - How can we make them better?



## Your Input

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- **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

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- **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

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- **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.

# NIH Lasker Clinical Research Scholars Program

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## Program Candidates:

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

# NIH Lasker Clinical Research Scholars Program

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## 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.

# NIH Lasker Clinical Research Scholars Program



## 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.

# NIH Lasker Clinical Research Scholars Program

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## **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

# NIH Lasker Clinical Research Scholars Program

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## **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

# NIH Lasker Clinical Research Scholars Program

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## **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)



## Your Input

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# 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?