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# *The NIH Clinical Center*

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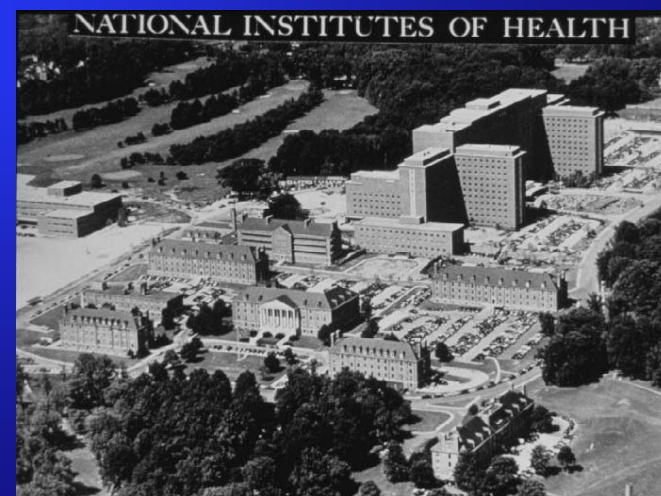




# *The National Institutes of Health*

## Overview

- Established by an act of Congress in 1887
- Comprised of 19 Institutes and Centers
- Divided into intramural and extramural programs
- Over the past seven years, the clinical research mission of the NIH was enhanced substantially under the leadership of Dr. Harold Varmus and, now, by Dr. Elias Zerhouni

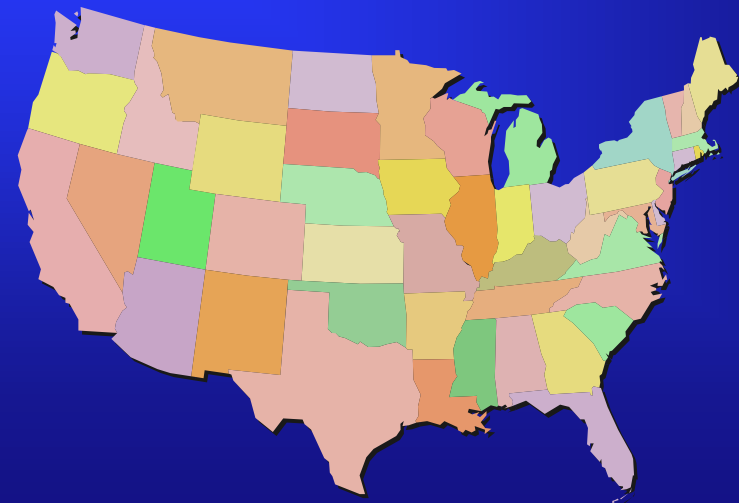




# *The National Institutes of Health*

## Extramural Program Overview

- Approximately 80% to 85% of the total NIH budget is allocated to the Extramural programs of the Institutes
- Grants for academic medical center and other institutions
- Funding provided for the General Clinical Research Centers (GCRCs) throughout the United States



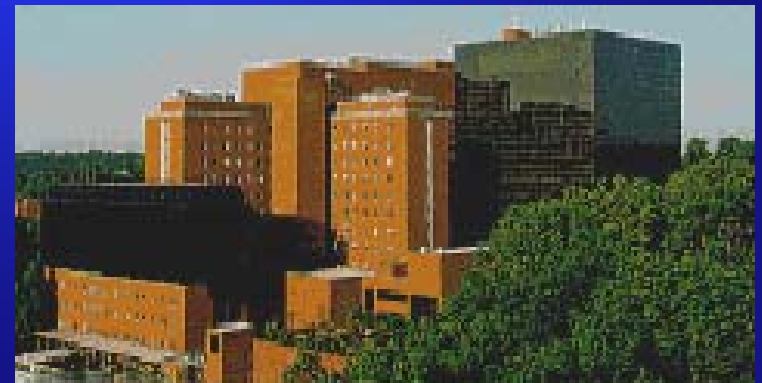


# *The National Institutes of Health*

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## **Intramural Program Overview**

- Approximately 10% of the total NIH budget is allocated to the Intramural programs of the Institutes.
- The campus covers 302 acres with over 50 buildings.
- Intramural science includes basic and clinical research
- 15 of the 19 Institutes and Centers have active clinical research programs in the CC.
- Clinical investigators from the 15 Institutes admit patient-volunteers to the CC to participate in research protocols.



# *The Warren Grant Magnuson Clinical Center*



## Clinical Center Overview

- Opened in 1953
- Currently 254 bed capacity
- \$331 million annual operating budget; approximately 1900 FTEs
- Building 10 houses approximately 40% of laboratory space on campus and more than 50% of NIH-funded general clinical research center beds in the U.S.
- Support over 1100 active clinical research protocols
- Approximately 1200 credentialed physicians
- Admitted approximately 6,539 admissions and scheduled 74,267 outpatient visits in FY02





# *The Warren Grant Magnuson Clinical Center*

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## **Mission**

The Clinical Center is the clinical research facility of the NIH. It provides patient care, services, training, and the environment in which NIH clinician-scientists creatively translate emerging knowledge into better understanding, detection, treatment, and prevention of human diseases.

## **Vision**

The Clinical Center serves as an international model of collaborative excellence and innovation in the design, conduct, training, and impact of clinical research.



# *The Warren Grant Magnuson Clinical Center*

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## Selected Accomplishments

- Lithium for bipolar disorders
- Blood tests for AIDS, hepatitis
- First gene therapy (ADA Deficiency)
- *H. influenzae* Type b vaccine; hepatitis B vaccine
- Treatment of sickle cell disease with hydroxyurea
- Pathogenesis and treatment of AIDS
- Chemotherapy and immunotherapy for cancer
- First successful artificial heart valve
- Immunosuppressive therapy for nonmalignant diseases (lupus, Wegener's granulomatosis, midline granuloma)



# *The Warren Grant Magnuson Clinical Center*

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## Protocol-Centered Patient Care

- The primary mission of the CC (i.e., clinical research) is distinctly different from most hospitals' missions; thus the relationship to our patients is also different
- Patients come to the CC from every state in the U.S. and from all over the world
- All patients admitted to the CC are participants in one or more ongoing clinical research protocols; thus, most care is driven directly from the protocol



# *The Warren Grant Magnuson Clinical Center*

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## Protocols by Type

Clinical Trials	540	(48%)
Natural History	519	(46%)
Screening	45	(4%)
Training	23	(2%)
Total	<u>1127</u>	



# *The Warren Grant Magnuson Clinical Center*

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## Clinical Trials by Phase

Phase I (toxicity)	215	(40%)
Phase II (activity)	263	(49%)
Phase III (efficacy)	44	(8%)
Phase IV (safety)	18	(2%)
Total	<u>540</u>	



# *The Warren Grant Magnuson Clinical Center*

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## *Specialized Clinical Research Support Services*

- Protocol Services Center
- Expanded IND Support
- Clinical Epidemiology/Biostatistics
- Cell Processing
- Clinical Research Informatics
- Telemedicine
- Radioligand Development
- Digital Imaging – RIS/PACS
- Imaging in the Operating Room
- Standards for Clinical Research
- Assisted Protocol Writing
- Protocol Mapping



# *The Warren Grant Magnuson Clinical Center*

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## *Specialized Patient - Centered Care and Support*

- Pain and Palliative Care Service
- Internal Medicine Service
- Pediatric Service
- Patient Representative
- Children's Inn
- Family Lodge
- Patient Recruitment/Public Liaison Services
- Proactive Patient Safety Program

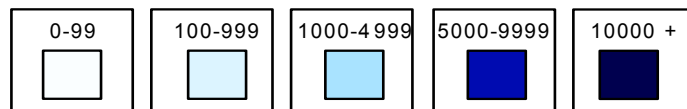
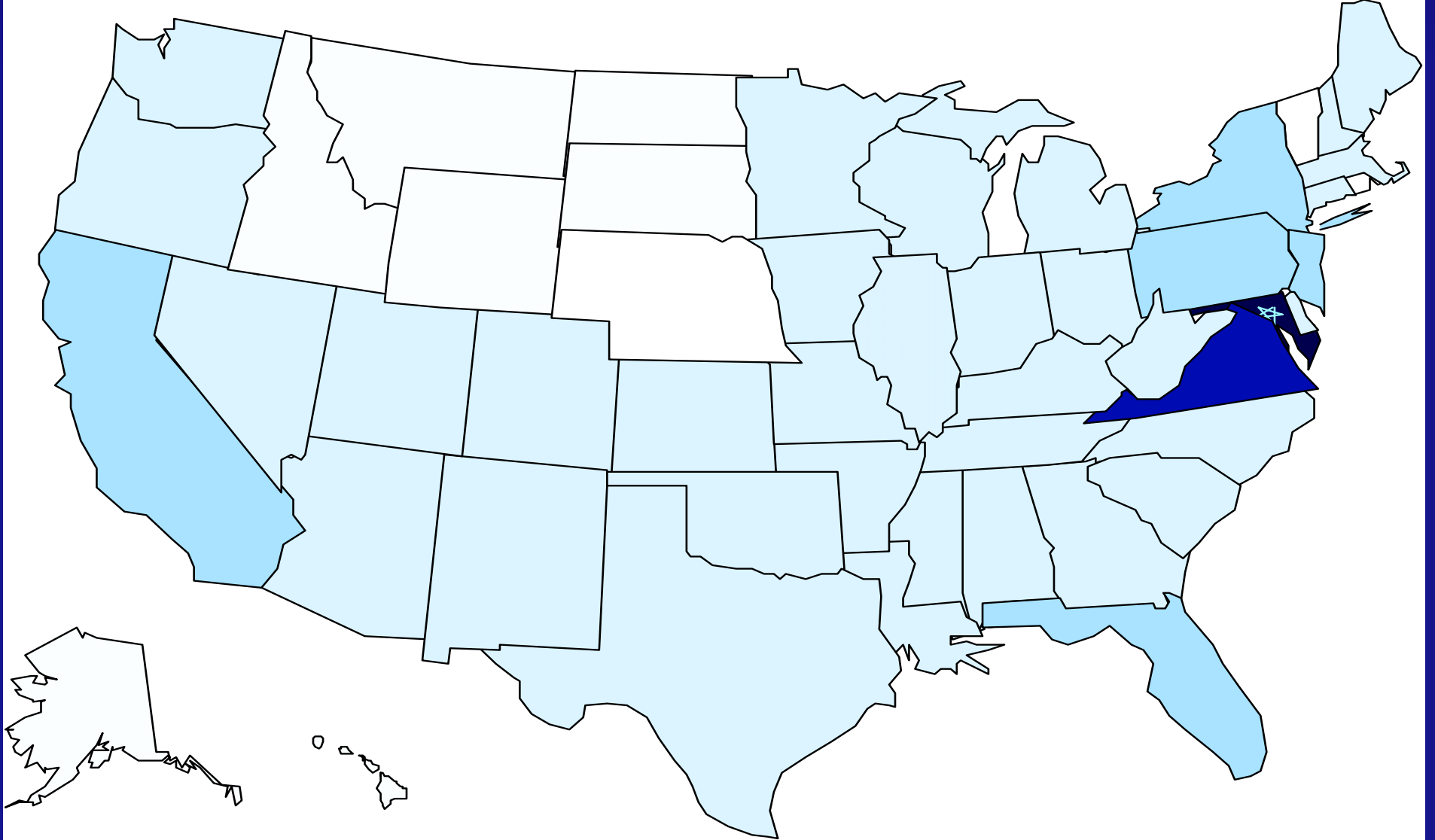


# *The Warren Grant Magnuson Clinical Center*

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## Protocol-Centered Patient Care

- Historically, patients were referred for care by their primary physicians and/or by tertiary referral centers; more recently, many patients are self-referring (a substantial fraction via the World Wide Web)
- Since our patients volunteer for clinical studies, all care is provided free of charge



*Home States of all Active Clinical Center Patients  
December 31, 1999*



# *The Warren Grant Magnuson Clinical Center*

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## *Patient Care at the Clinical Center*

- The CC is not a “full-service” hospital – we have no emergency room, obstetrics service, in house orthopedic surgery, etc
- Routine, non-emergency patient care services, not related to the protocol are not provided by the CC but are managed in collaboration with the patient’s referring physician



# *Standards for Clinical Research Within the NIH Intramural Program*

STANDARDS  
FOR CLINICAL RESEARCH  
WITHIN THE  
NIH  
INTRAMURAL RESEARCH  
PROGRAM



- Clinical Informatics, Data Management and Protocol Tracking
- Biostatistics Support
- Quality Assurance and Quality Control
- Protocol Review
- Human Resources and Physical Plant
- Training and Education



# *Patient Recruitment and Public Liaison Office*

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## Recruitment/Communications

- Referral support for the NIH intramural program
  - Nurses manage referral hotline
  - Conduct preliminary screening
  - Refer physicians/patients to appropriate NIH contact person
- Community outreach to enhance diverse participation
- Public education regarding patient recruitment

1-800-411-1222

[prpl@cc.nih.gov](mailto:prpl@cc.nih.gov)



# *Building the NIH Curriculum in Clinical Research*

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## Clinical Research Training

- Basic Clinical Investigator Training
- Introduction to the Principles & Practice of Clinical Research
- Clinical Pharmacology
- Ethical and Regulatory Aspects of Human Subjects Research
- NIH/Duke Masters of Health Sciences Program

*A look toward the future...*



## Mark O. Hatfield Clinical Research Center

- ❖ 243 Beds
- ❖ 77 Day Hospital Stations
- ❖ Flexibility