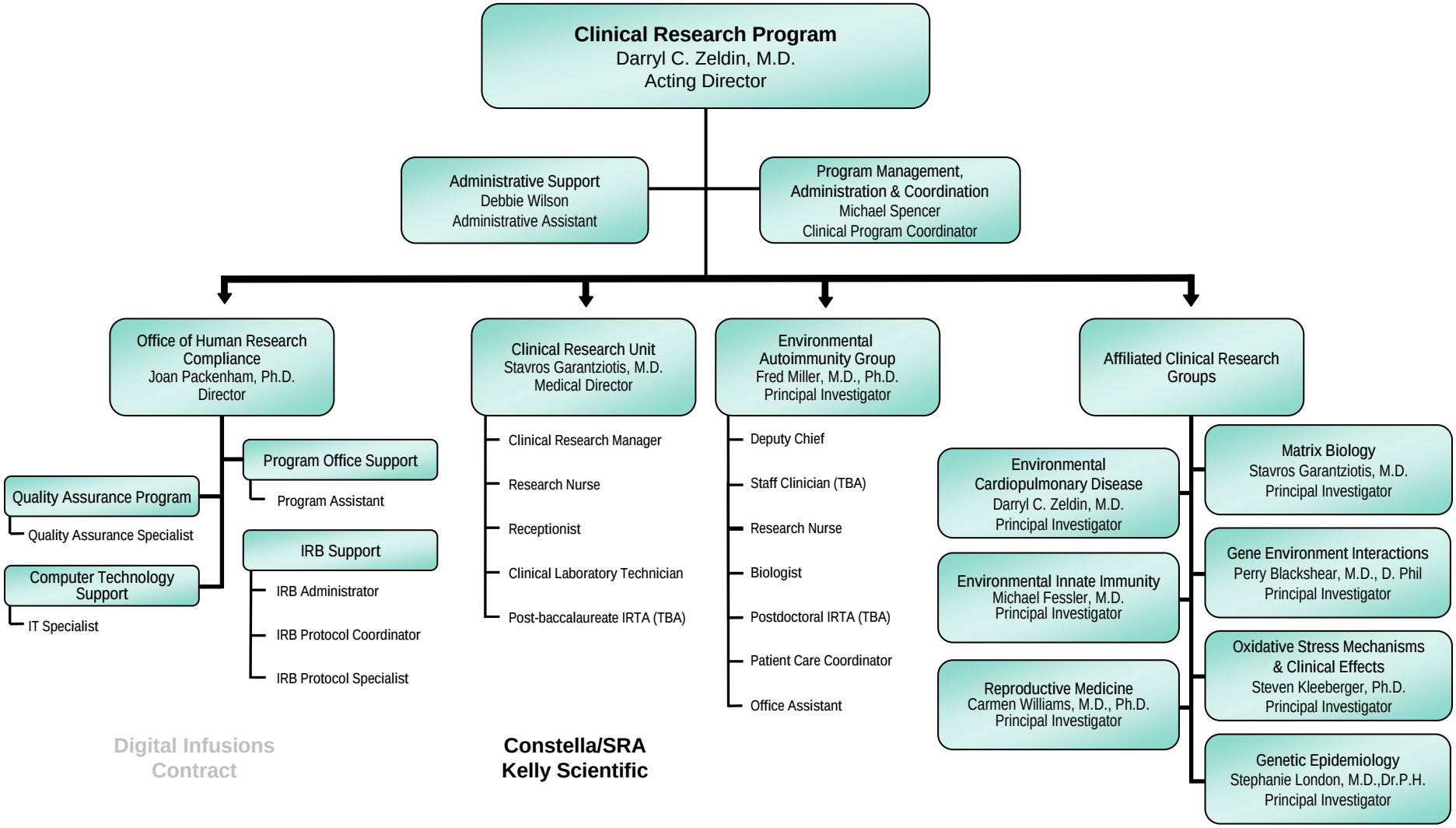
The NIEHS Clinical Research Program:
Report to NAEHS Council - September 15, 2009

Organizational Chart



Digital Infusions Contract

Constella/SRA Kelly Scientific

NIEHS
National Institute of Environmental Health Sciences

Grand Opening
of the
NIEHS Clinical Research Unit

July 27, 2009 • 11:00 a.m.

National Institute of Environmental Health Sciences
David P. Rall Building • Rodbell Auditorium
111 T.W. Alexander Drive
Research Triangle Park, North Carolina

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Order of Service

Master of Ceremonies
Joe Graedon
The People's Pharmacy

Opening Remarks
Linda Birnbaum, Ph.D.
Director, National Institute of Environmental Health Sciences
and National Toxicology Program

Greetings From NIH
Michael Gottesman, M.D.
NIH Deputy Director for Intramural Research

A Local Partner's Perspective
Robert Califf, M.D.
Vice Chancellor for Clinical Research, Duke University

Officials
Kay Hagan, U.S. Senator from N.C.
David Price, U.S. Representative from N.C., 4th District
Bob Etheridge, U.S. Representative from N.C., 2nd District
Brad Miller, U.S. Representative from N.C., 13th District
Walter Dalton, Lieutenant Governor of N.C.
Lanier Cansler, N.C. Secretary of Health and Human Services
Michael Page, Durham County Commissioner
William Bell, Durham Mayor

Award Presentations
Darryl Zeldin, M.D.
Acting Director, NIEHS Clinical Research Program

Adjourn to NIEHS Clinical Research Unit for Ribbon-Cutting Ceremony


NIEHS

Clinical Research Symposium

Symposium Moderator

Stavros Garantziotis, M.D.
Staff Clinician
Medical Director, Clinical Research Unit

1:30 P.M.

Robert Califf, M.D.
Vice Chancellor for Clinical Research, Duke University

"Addressing Key Issues on Evaluating Mechanisms of Disease in Humans"

2:00 P.M.

Philip Landrigan, M.D., M.Sc.
Professor and Chair of Community and Preventive Medicine
Mt. Sinai Medical Center

"The National Children's Study — The Need and the Promise"

2:30 P.M

Franck Mauvais-Jarvis, M.D., Ph.D.
Associate Professor of Medicine
Division of Endocrinology, Metabolism and Molecular Medicine
Northwestern University

"Estrogen Receptors and Pancreatic Islet Survival in Diabetes:
An Example of Bidirectional Translational Research"

NIEHS Clinical Research Unit
Active Protocols

Innate Immunity Signal Transduction in Human Leukocytes

Principal Investigators: Fessler, Resnick, Mason, Bell, Cidlowski, Blackshear, Garantziotis

Pathogenic Studies In Families With Twins Or Siblings Discordant For Systemic Rheumatic Disorders

Principal Investigators: Miller, Rider

External Clinical Advisory Council

- First meeting on July 28, 2009
- Council asked to provide guidance on three major issues
  - Overall direction of the Clinical Research Program
  - How the Clinical Research Program can best interact with NIEHS intramural and extramural investigators
  - Best strategies for future growth of the Clinical Research Program

External Clinical Advisory Council

Overall Direction of the Clinical Research Program

- Creation of 1-2 “Signature Programs” which will distinguish us from other clinical programs at NIH and nationally
  - Environmental relevance
  - Public health promotion and disease prevention
  - Take advantage of existing expertise
- Collaboration with NTP and other governmental agencies (e.g. EPA, CDC) for optimal translational impact
- Utilization of existing databases and cohorts (e.g. Sister Study, Environmental Polymorphism Registry)
- Development of a research program that focuses on better understanding health disparities - environmental exposures, disproportionate prevalence/morbidity of disease in certain populations

External Clinical Advisory Council

Best Model for Interaction with DIR and DERT

- Collaborate with basic science leaders at NIEHS to develop multidisciplinary projects that address interesting clinical questions
- Encourage recruitment of tenure-track investigators with training in clinical-translational research (MD or MD/PhD)
- Provide incentives for clinical-translational research success during the tenure process
- Provide competitive funding mechanism to support investigator-initiated, clinical-translational research projects
- Offer workshops and seminar series to enhance awareness of clinical-translational research among basic scientists at NIEHS
- Provide the necessary administrative and operational support for clinical research studies at NIEHS

External Clinical Advisory Council

Best Strategies for Programmatic Growth

- Provide additional training opportunities for undergraduates, medical students and clinical fellows
- Create a visiting clinical scholar program
- Hire a physician-scientist with expertise in Environmental Medicine or Occupational Medicine and develop a clinical-translational program in this area
- Use short and long-term benchmarks to gauge success of the program and track its progress

External Clinical Advisory Council

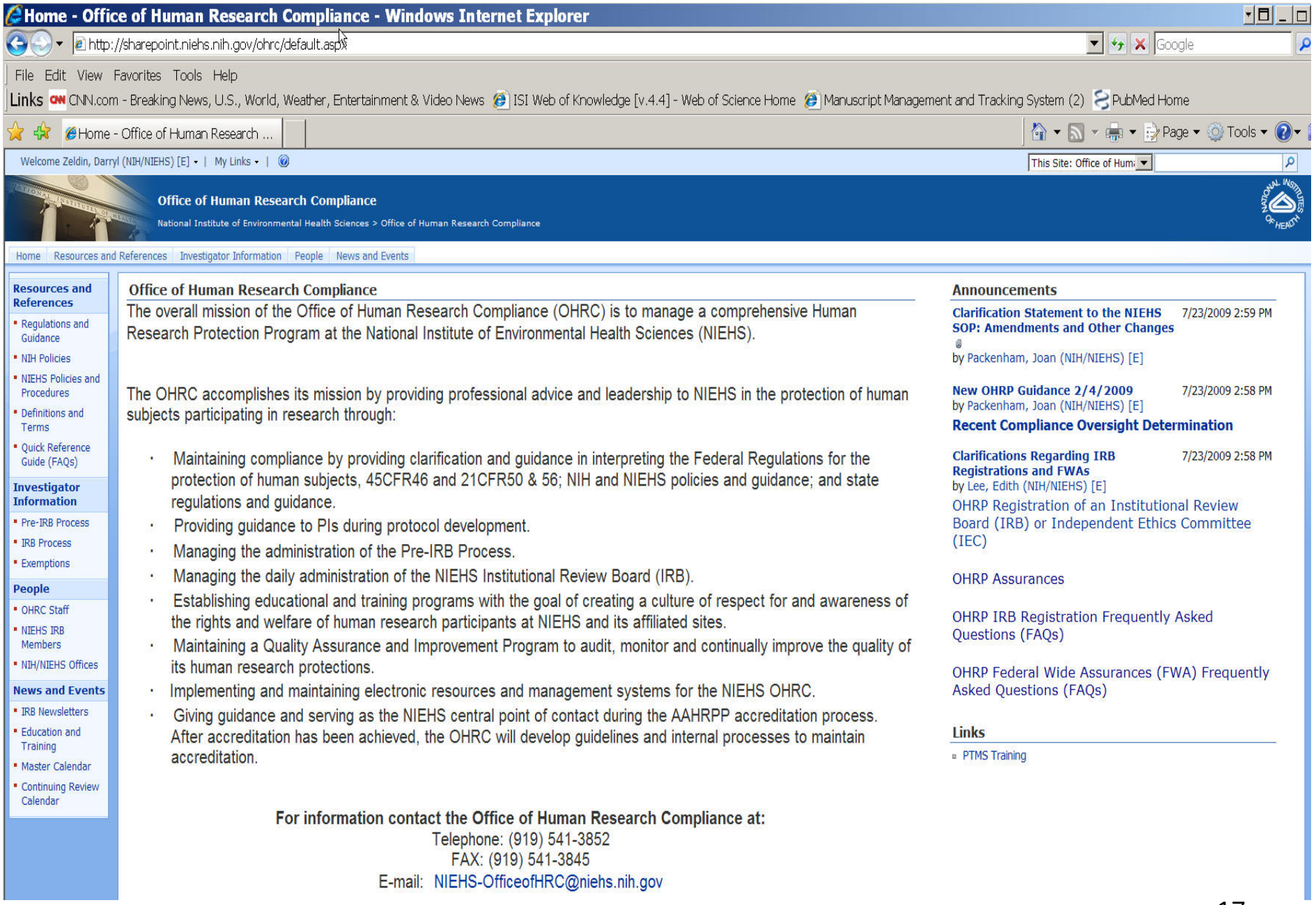
Key Recommendations for Future Development

- Distinguish the CRU from other clinical research units by emphasizing its environmental focus
- Begin with small, highly achievable projects and develop larger, more complex studies over time
- Raise internal awareness of the types of clinical research studies that are being conducted in the CRU
- Develop incentives and inducements to encourage participation in clinical-translational research by NIEHS investigators
- Develop clinical-translational protocols in selected areas of strength (e.g. respiratory, reproductive, genetics)
- Assume leadership role in the development of a new model for conducting environmentally relevant, clinical-translational research studies

Office of Human Research Compliance

Office of Human Research Compliance

- Consolidated staff in the new CRU – close proximity to IRB Chair and clinical investigators
- 54 active clinical protocols
  - 36 Epidemiology, 18 non-Epidemiology
  - 3 initial reviews, 15 continuing reviews, 11 protocol amendments, and 2 protocol deviations since last Council meeting
- 2 new IRB members added
- 2 reliance agreements with other institutions
- 2 due-diligence audits performed
- IRB and OHRC retreats
- Launch of the OHRC Sharepoint website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http://sharepoint.niehs.nih.gov/ohrc/default.aspx
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Welcome Zeldin, Darryl (NIH/NIEHS) [E] | My Links |
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NIH Policies
NIEHS Policies and Procedures
Definitions and Terms
Quick Reference Guide (FAQs)
Investigator Information
Pre-IRB Process
IRB Process
Exemptions
People
OHRC Staff
NIEHS IRB Members
NIH/NIEHS Offices
News and Events
IRB Newsletters
Education and Training
Master Calendar
Continuing Review Calendar
Office of Human Research Compliance
The overall mission of the Office of Human Research Compliance (OHRC) is to manage a comprehensive Human Research Protection Program at the National Institute of Environmental Health Sciences (NIEHS).
The OHRC accomplishes its mission by providing professional advice and leadership to NIEHS in the protection of human subjects participating in research through:
Maintaining compliance by providing clarification and guidance in interpreting the Federal Regulations for the protection of human subjects, 45CFR46 and 21CFR50 & 56; NIH and NIEHS policies and guidance; and state regulations and guidance.
Providing guidance to PIs during protocol development.
Managing the administration of the Pre-IRB Process.
Managing the daily administration of the NIEHS Institutional Review Board (IRB).
Establishing educational and training programs with the goal of creating a culture of respect for and awareness of the rights and welfare of human research participants at NIEHS and its affiliated sites.
Maintaining a Quality Assurance and Improvement Program to audit, monitor and continually improve the quality of its human research protections.
Implementing and maintaining electronic resources and management systems for the NIEHS OHRC.
Giving guidance and serving as the NIEHS central point of contact during the AAHRPP accreditation process. After accreditation has been achieved, the OHRC will develop guidelines and internal processes to maintain accreditation.
For information contact the Office of Human Research Compliance at:
Telephone: (919) 541-3852
FAX: (919) 541-3845
E-mail: NIEHS-OfficeofHRC@niehs.nih.gov
Announcements
Clarification Statement to the NIEHS SOP: Amendments and Other Changes 7/23/2009 2:59 PM
by Packenham, Joan (NIH/NIEHS) [E]
New OHRP Guidance 2/4/2009 7/23/2009 2:58 PM
by Packenham, Joan (NIH/NIEHS) [E]
Recent Compliance Oversight Determination
Clarifications Regarding IRB Registrations and FWAs 7/23/2009 2:58 PM
by Lee, Edith (NIH/NIEHS) [E]
OHRP Registration of an Institutional Review Board (IRB) or Independent Ethics Committee (IEC)
OHRP Assurances
OHRP IRB Registration Frequently Asked Questions (FAQs)
OHRP Federal Wide Assurances (FWA) Frequently Asked Questions (FAQs)
Links
PTMS Training

QUESTIONS ??