

**WELCOME to WAYNE
Basic and Clinical Research**

**Daniel A. Walz, Ph.D.
Associate Dean for Research
Professor of Physiology**

April 30, 2009

**Research Office
1261 Scott Hall
577-9553**

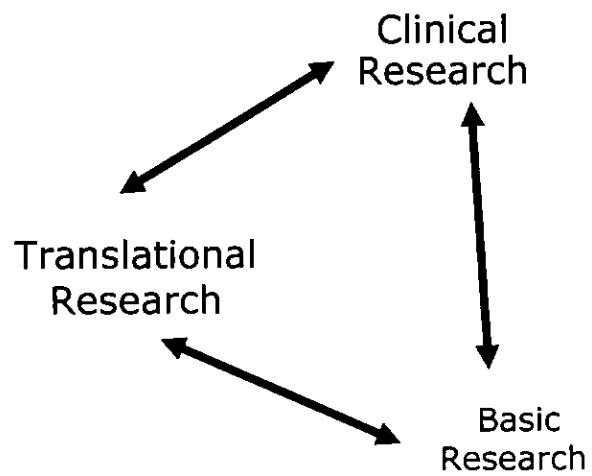
Michael Diamond, M.D.: Assistant Dean for
Clinical Research (993-4523)
mdiamond@med.wayne.edu

Anna Spiroff: Grants Advisory Coordinator (577-
7588) aspiroff@med.wayne.edu

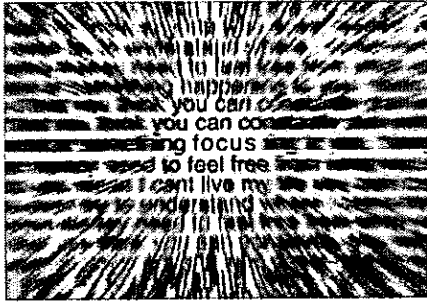
Joan Dunbar, Ph.D.: Director, Biotechnology
Development (577-5542)
jcdunbar@med.wayne.edu

Important Website

- www.hhas.gov
- www.nih.gov



Focus Please



- Do I have a research area of focus?

What to Do First?

- Preparatory work
- Grants
 - Know the role/duties you have agreed to
 - Clarify your role **IN WRITING**
- Papers
 - Specify authorship prior to beginning work
 - Clarify authorship depending on journal
- Do the work promised in a timely way

Getting Started

- Hypothesis driven
 - investigator initiated
 - trial sites (multicenter, industry, CRN, etc.)
- Background, pilot information
- Protocol generation
- Statistical consultation
- Budget
- Regulatory processes (IRB, GCP, etc.)
- Funding sources (intra- &/or extramural)



Roles

- Investigators
 - Principal investigator
 - Co-investigator
 - Collaborator
 - Other
- Mentors
 - Who are they?
 - Who needs them?



Resources

- University
- School of Medicine
 - Departments/Divisions
 - CTSA
 - Institutes
- Industry
- Extramural funding

Issues

- Laboratory based investigations
- Clinical trials
 - Investigator initiated vs industry trials
 - Inpatient vs outpatient
- Regulatory support
- Financial/Budgetary support
- Database studies
- Statistical support

Factors in Success: investigator

- Time management
 - “protected time” vs “dedicated time”
- Sufficient Training
- Sufficient, trained and cooperative staff
- Data management system

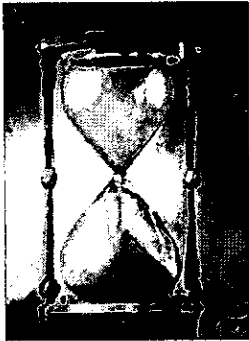
Factors in Success: institution

- Recognition of collaboration
 - Funding agency
 - Academic “value added”
- Collegiality and building alliances
- Foresight and planning

Factors in Success: subjects

- Recruitment and retention
 - Subjects
 - Personnel
- Partnership with community
- Adaptive strategies to idiosyncrasies of population, sites, study, etc.

Factors for Success



- Commitment to clinical research
 - FIRE IN THE BELLY
- Ability to deal with frustration and challenges
- Time

Time

- **Time is your friend**
- **Time is your enemy**

Issues in Clinical Research

- Management and governance
- Recruitment and retention
- Training and professional development
- Data management
- Information technology
- Financial practices

Questions?