WELCOME to WAYNE
Basic and Clinical Research

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

September 30, 2010
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?
Clinical Research

Translational Research

Basic Research
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
Time

- Time is your friend
- Time is your enemy
Questions?
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
Issues in Clinical Research

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