Getting Started In Research
on the MCV Campus

John N Clore MD
Professor of Medicine and
Associate Vice President for Clinical Research
Director, CCTR
Objectives

- To review the necessary elements of a research protocol
- To find the resources available at VCU to successfully submit the protocol
- To reduce the barriers to success
So you have this great idea!
Glucose

P → ChREBP

P → Mlx → ChREBP

ChREBP

SREBP-1c

Insulin

Insig-1

SCAP

SREBP-1c

SRE

ChoRE

Lipogenic gene expression
Hypothesis

- Increased De Novo Lipogenesis increases risk for insulin resistance and Type 2 diabetes mellitus
Specific Aims

- To examine the relationship between circulating concentrations of SFA, de novo lipogenesis and insulin resistance in individuals at risk for diabetes mellitus (human study)

- To examine the impact of community based initiatives to reduce high-fructose corn syrup consumption
Hypothesis
Specific Aims
Background and Significance
Preliminary Progress
Research Method and Design
Statistical Analysis
References
Study Design - Study 1

- To examine the relationship between circulating concentrations of SFA, de novo lipogenesis and insulin resistance in individuals at risk for diabetes mellitus (human study)
What do we have to do to answer this question?
Methods and Resources Needed

- How do I measure insulin resistance?
- How do I measure DNL?
- Where can I do this study?
- Where do I get the lab determinations done?
- Where will the research subjects come from?
- What is the primary endpoint of this study?
- What do I need to do to get approval for human research?
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Center for Clinical and Translational Research
1200 E Clay St

- www.cctr.vcu.edu
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Chris Gennings PhD
Pam Dillon Pharm D
Cornelia Ramsey PhD
Jake Wegelin PhD
Leroy Thacker PhD
Bonnie Quearry

SECOND FLOOR FURNITURE/POWER/VOICE/DATA PLAN
Research Incubator/ CCTR
Research Resources

- Clinical Research Center
- Core laboratories
  - Paul Fawcett PhD
- MATR
- Sample Processing Laboratories
- Molecular Diagnostics Lab
Research Resources

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  - Paul Fawcett PhD
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- Sample Processing Laboratories
- Molecular Diagnostics Lab
Specific Aims

To examine the impact of community based initiatives to reduce high-fructose corn syrup consumption
Methods and Resources Needed

- How do I measure insulin resistance?
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Clinical Trials at VCU

Discovering through research
Translating research to treatment
Delivering treatment to you

Did you know?
In 1993, a federal law was passed requiring that women and minorities be included in every clinical trial involving a disease that affects them.

Find a clinical trial at VCU

Virginia Commonwealth University conducts research studies and clinical trials in various divisions throughout the Medical Center including VCU Massey Cancer Center. Search for clinical trials at VCU here.

What is a clinical trial?
Research Subject Recruitment

- Clinical Trials @ VCU
- IRB approved protocols
- Brief description of the project
- Inclusion/exclusion criteria
- Contact info
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Biostatistical Considerations

- Need biostatistician to help write data analysis plan
- Include
  - Preliminary data analysis steps
  - Primary analysis plan
  - Secondary analysis plan
  - Sample size considerations
Biostatistical Considerations

- What is the primary endpoint?
- What sort of relationship is expected (between DNL and IR)? What about across groups (at risk for DM2; not at risk)?
- What preliminary data can be used for sample size and power estimation?
Biostatistical Considerations

Expected relationship:

- Insulin Resistance
- de novo lipogenesis

- Low risk
- High risk
Biostatistical Considerations

Sample size considerations

- Use literature values and/or preliminary data results
- Here, from preliminary data (means and standard deviations) on low risk group we make assumptions about high risk group.
- Either fix effect size and find power OR fix power and find effect size.
What about database support and informatics?

- REDCap
  - Tim Aro- GCRC
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Regulatory knowledge and support
Two things here:
1) GCRC website and description of DSMP and Human subjects concerns
http://www.vcuhealth.org/crc/proiinfo.htm

2) IRB website:
http://www.research.vcu.edu/orsp/index.htm
   a) IRB training
   b) Elements of the informed consent process
http://www.research.vcu.edu/forms/vcuirb.htm
Funding sources

- Federal Sources (the alphabet soup)
  - NIH
  - Other HHS
  - NSF
  - DoD
- Non-Profit Foundations
- Virginia Funding Opportunities
VCU Internal Funding Sources

- **A.D. Williams** (Application deadlines: Aug. 1, Nov. 1, Feb. 1, and May 1)

- **American Cancer Society Internal Grant** (Application deadline: April 1)

- **Clinical Research Feasibility Funds (CReFF)** (Application deadline: February 1)
Finding what is available

- Grants.gov:  www.grants.gov
- NIH:  funding opportunities at www.nih.gov
- NIH listserv:  listserv@list.nih.gov
- Catalog of Federal Domestic Assistance:  http://12.46.245.173/cfda/cfda.html
Getting help

- NIH grantwriting workshops
- Visit CCTR and Office of Research website
- Library training
- Find a mentor
Now What?

- What else do I need to do?
- Where do I need to submit the application?
Electronic Submission

Budget

http://www.research.vcu.edu/forms/osp.htm

- **Direct Costs (what you hope to get)**
  - Salary of PI (+31% fringes)
  - Salary of others involved in the research (+fringes)
  - Supplies
  - Travel etc

- **Indirect Costs (what the institution gets)**
Forms

- Of course there are forms!
  http://www.research.vcu.edu/forms/osp.htm

- The Greensheet
  http://www.research.vcu.edu/forms/osp.htm

- Conflict of Interest forms
Final Submission

- Greensheet and COI’s signed by all relevant people involved in the research
- Whole packet (forms, budget, greensheet, etc) goes to
  - Department
  - Dean’s office
  - Sponsored programs (last)
Conclusion

- Protocol
- Biostatistics
- IRB/IACUC
- Funding Source
- Budget
- Submission
  - IRB
  - GCRC, etc
  - OSPA
Questions ?