

Getting Started In Research on the MCV Campus

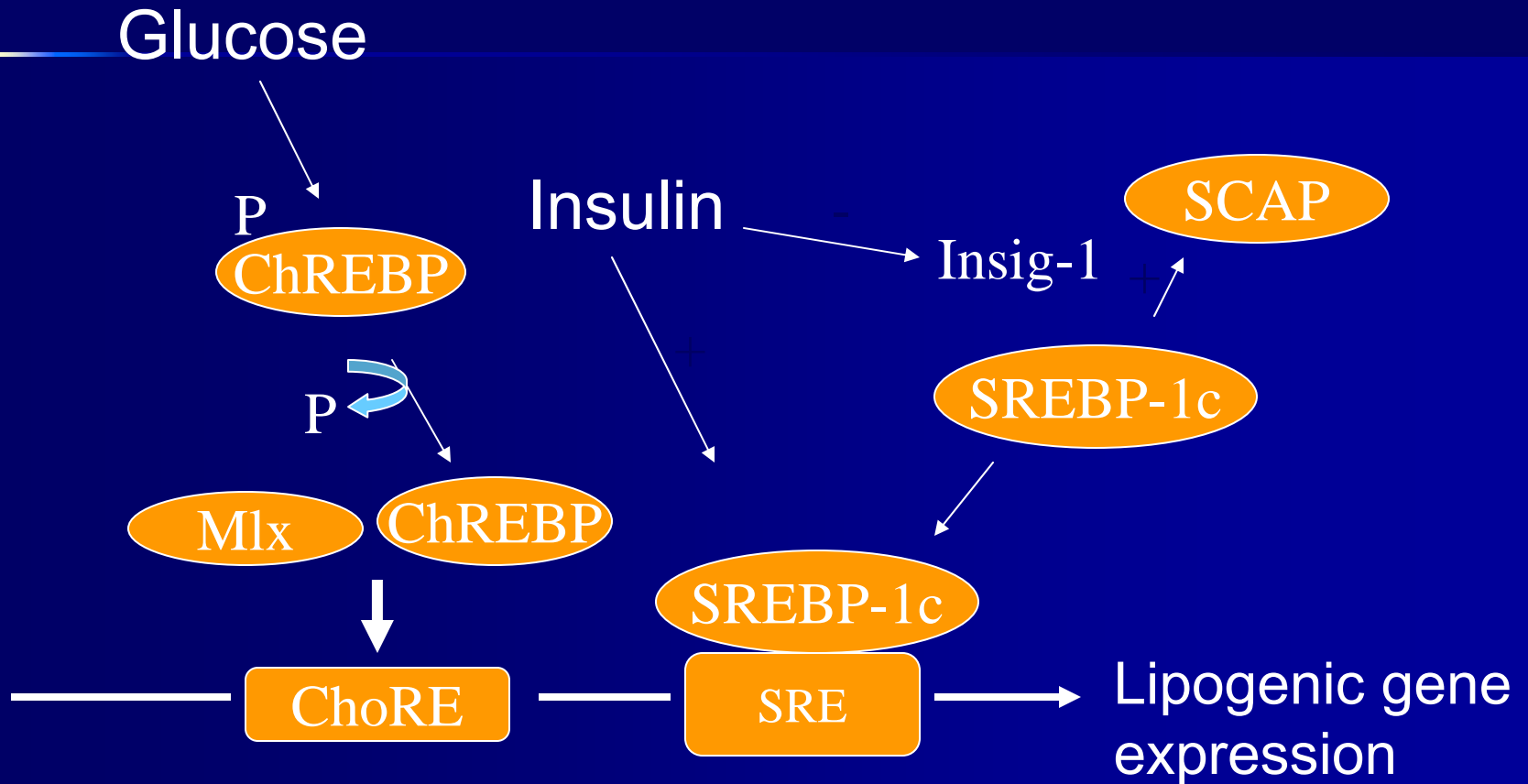
John N Clore MD
Professor of Medicine and
Associate Vice President for Clinical Research
Director, CCTR



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!



Hypothesis
Specific Aims
Background and Significance
Preliminary Progress
Research Method and Design
Statistical Analysis
References

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
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Study Design-Study 1

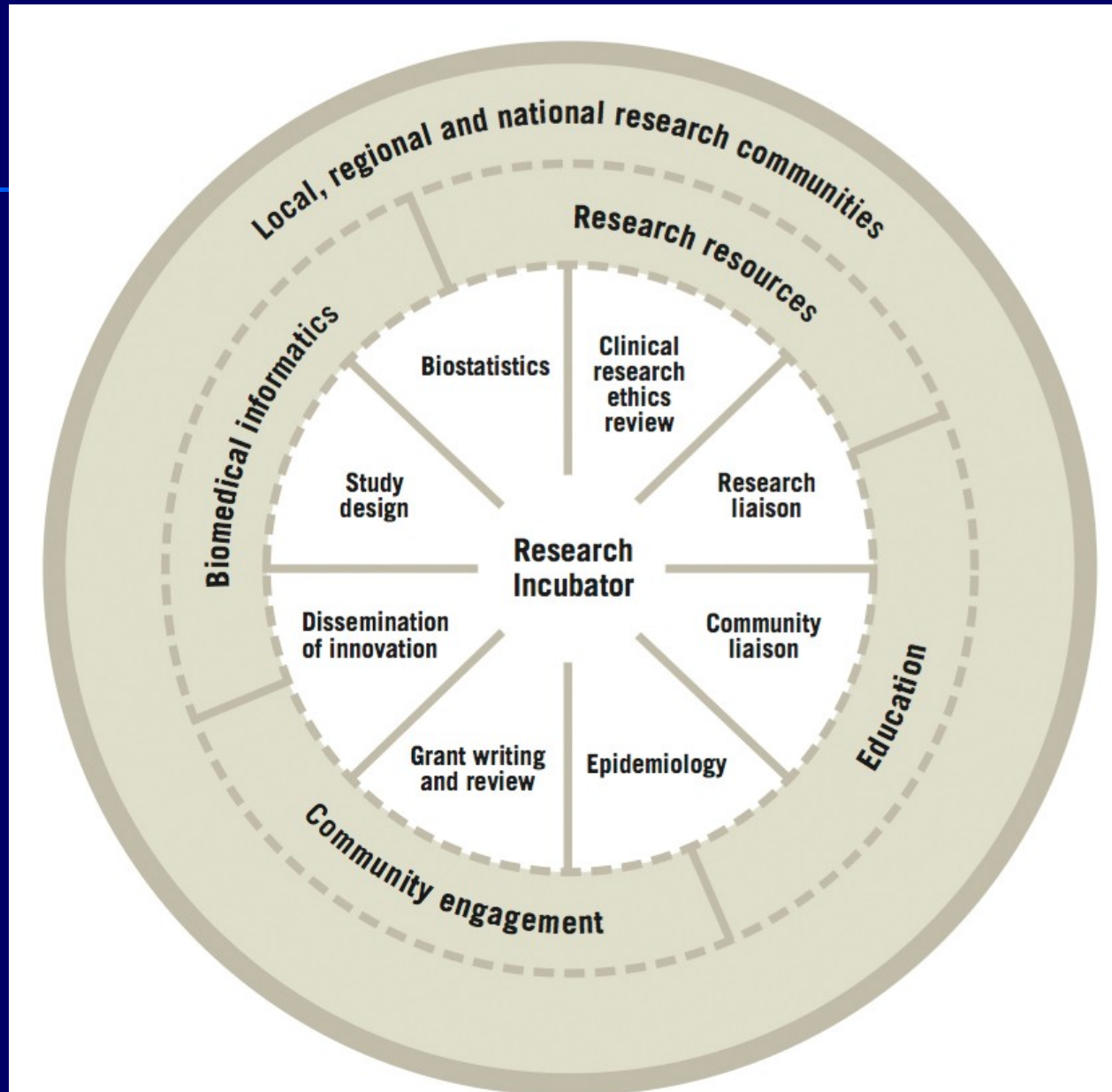
- To examine the relationship between circulating concentrations of SFA, de novo lipogenesis and insulin resistance in individuals at risk for diabetes mellitus (human study)

What do we have to do
to answer this question ?

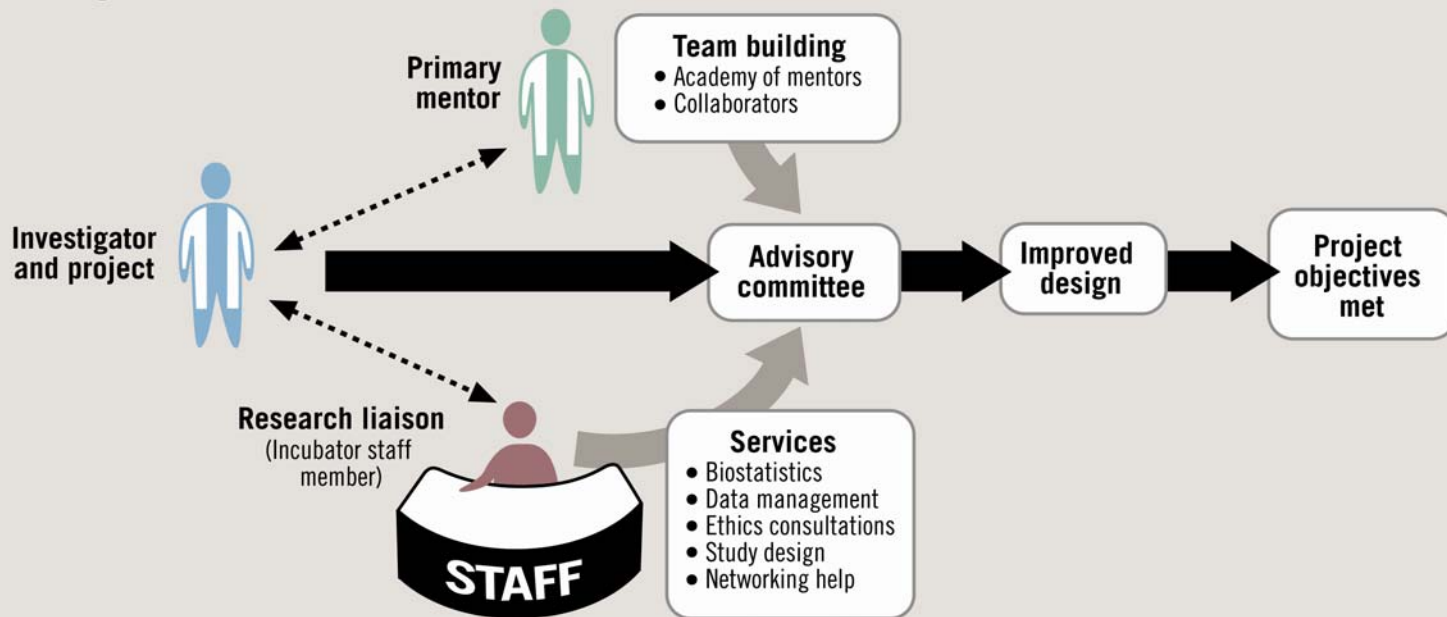
Methods and Resources Needed

- 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?

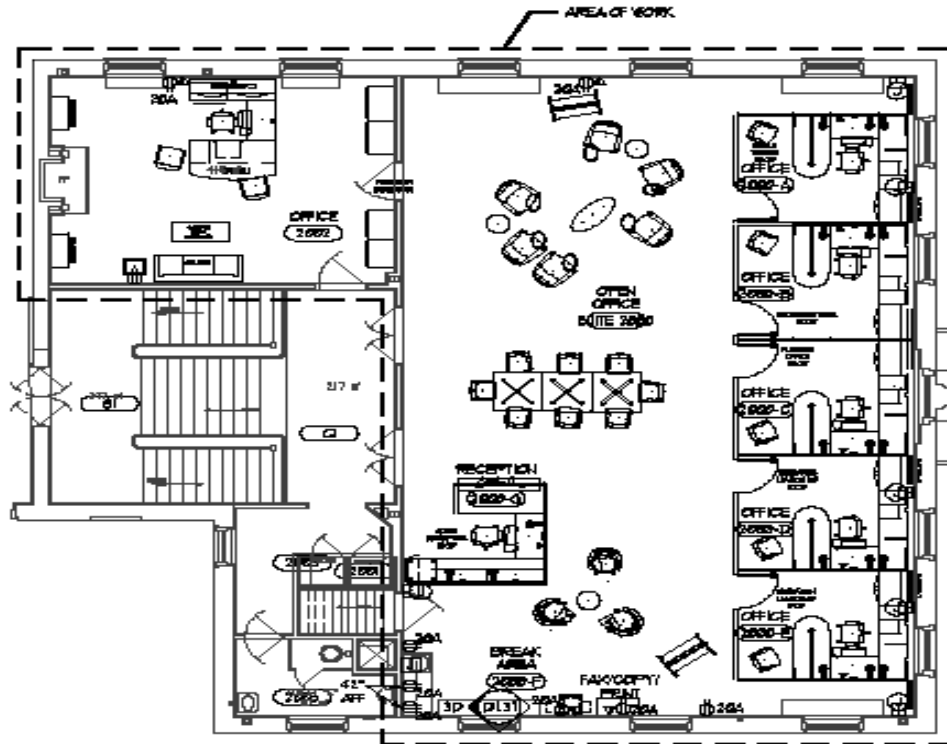
Research Incubator/CCTR



Design, biostatistics and clinical research ethics



Center for Clinical and Translational Research 1200 E Clay St



Pam Dillon Pharm D

Cornelia Ramsey PhD

Jake Wegelin PhD

Leroy Thacker PhD

Bonnie Quearry

SECOND FLOOR FURNITURE/POWER/VOICE/DATA PLAN

SCALE: 1/8" = 1'-0"

PLAN
NORTH

5A

D191

Center for Clinical and Translational Research 1200 E Clay St

- www.cctr.vcu.edu



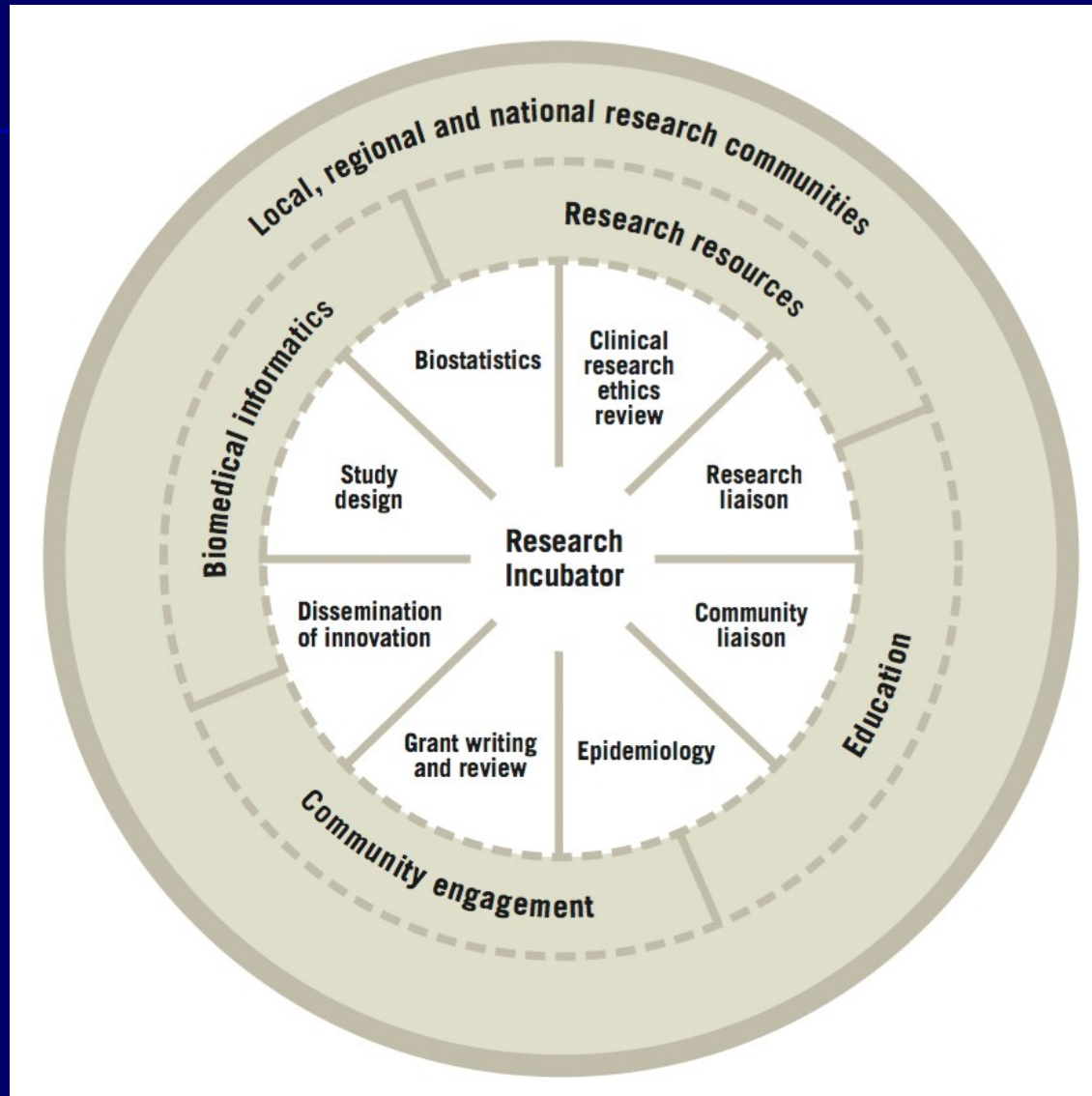
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Research Incubator/CCTR



General Clinical Research Center

<http://www.vcuhealth.org/crc/>

GCRC – North Hospital 8th Floor

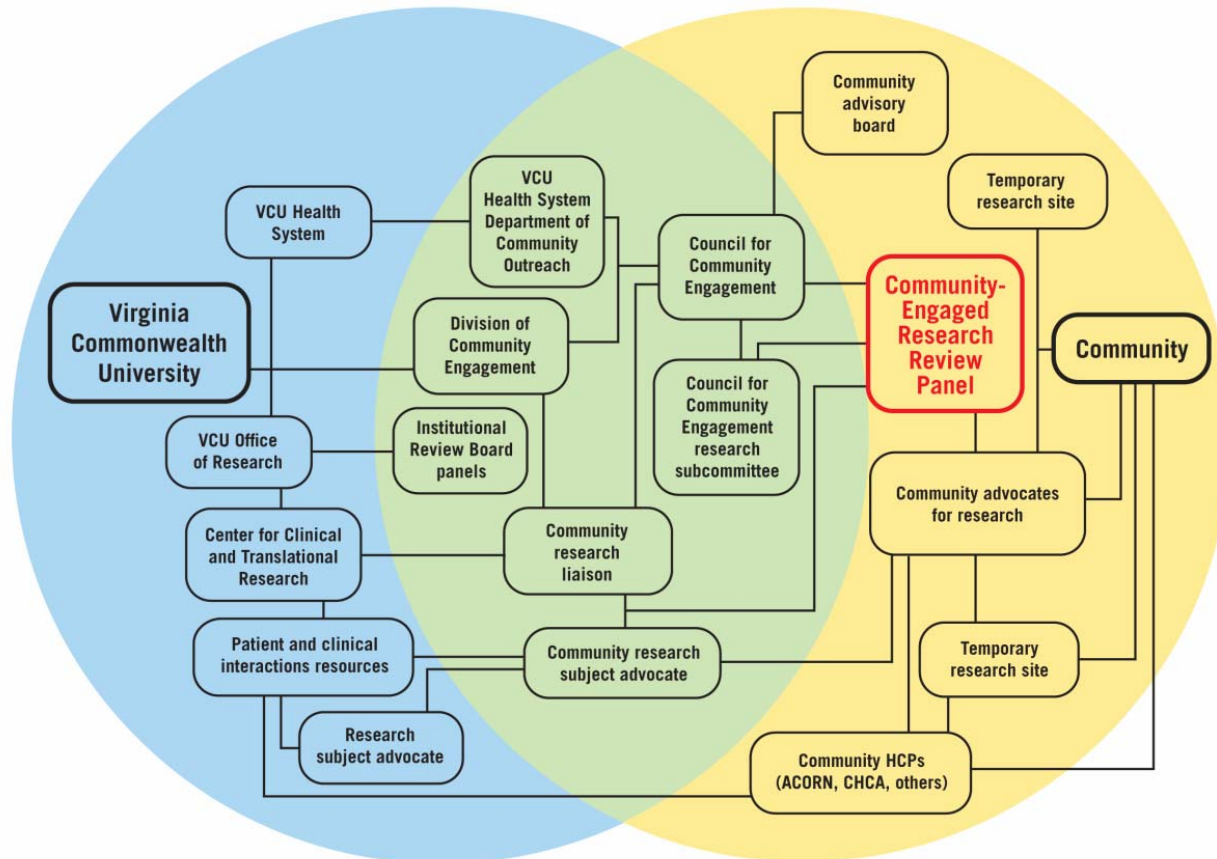


Specific Aims

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

Community involvement

● University
 ● University/community interface
 ● Community



Methods and Resources Needed

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- 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?

Biostatistical
Resources
at
VCU

Chris Gennings PhD

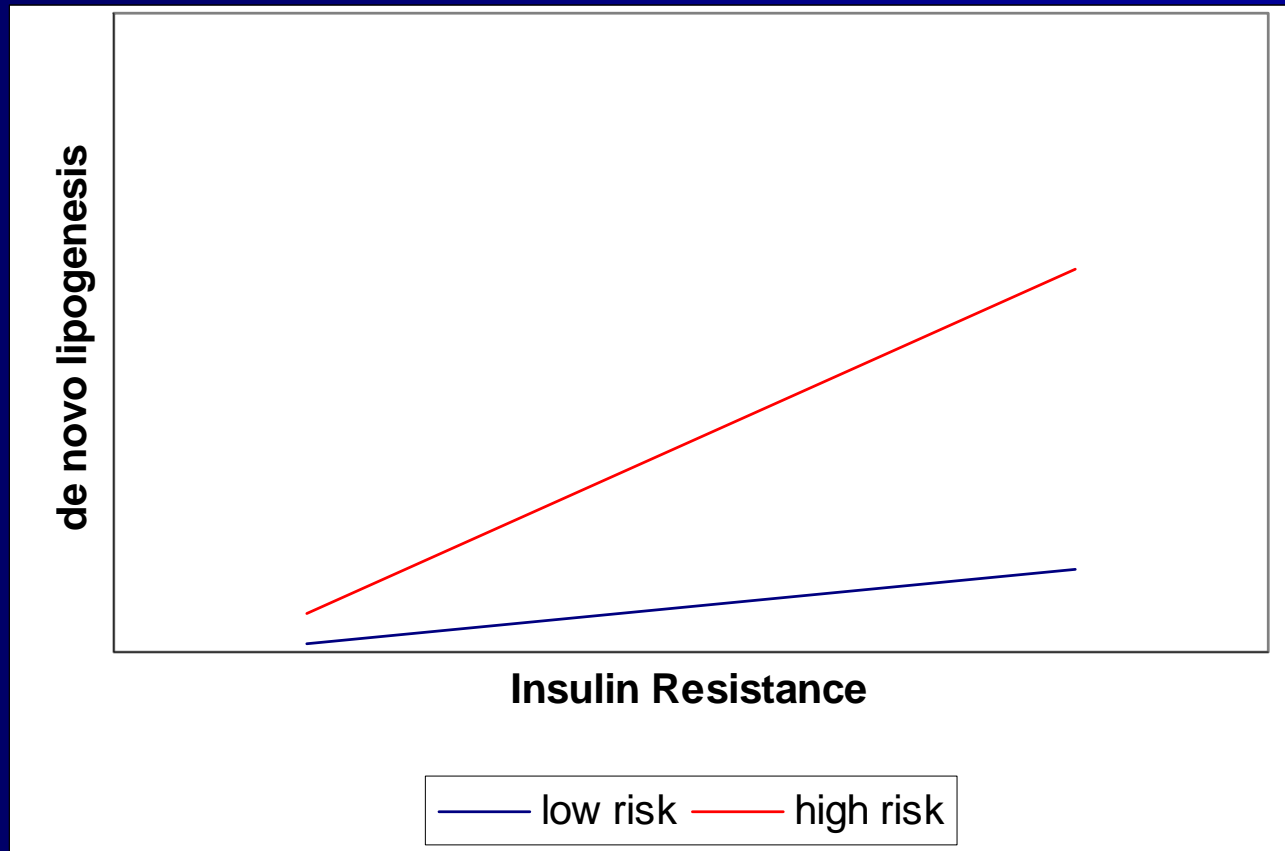
Biostatistical Considerations

- 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



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.

BioMedical Informatics Core for Support of Clinical & Translational Research at VCU

Basic Research



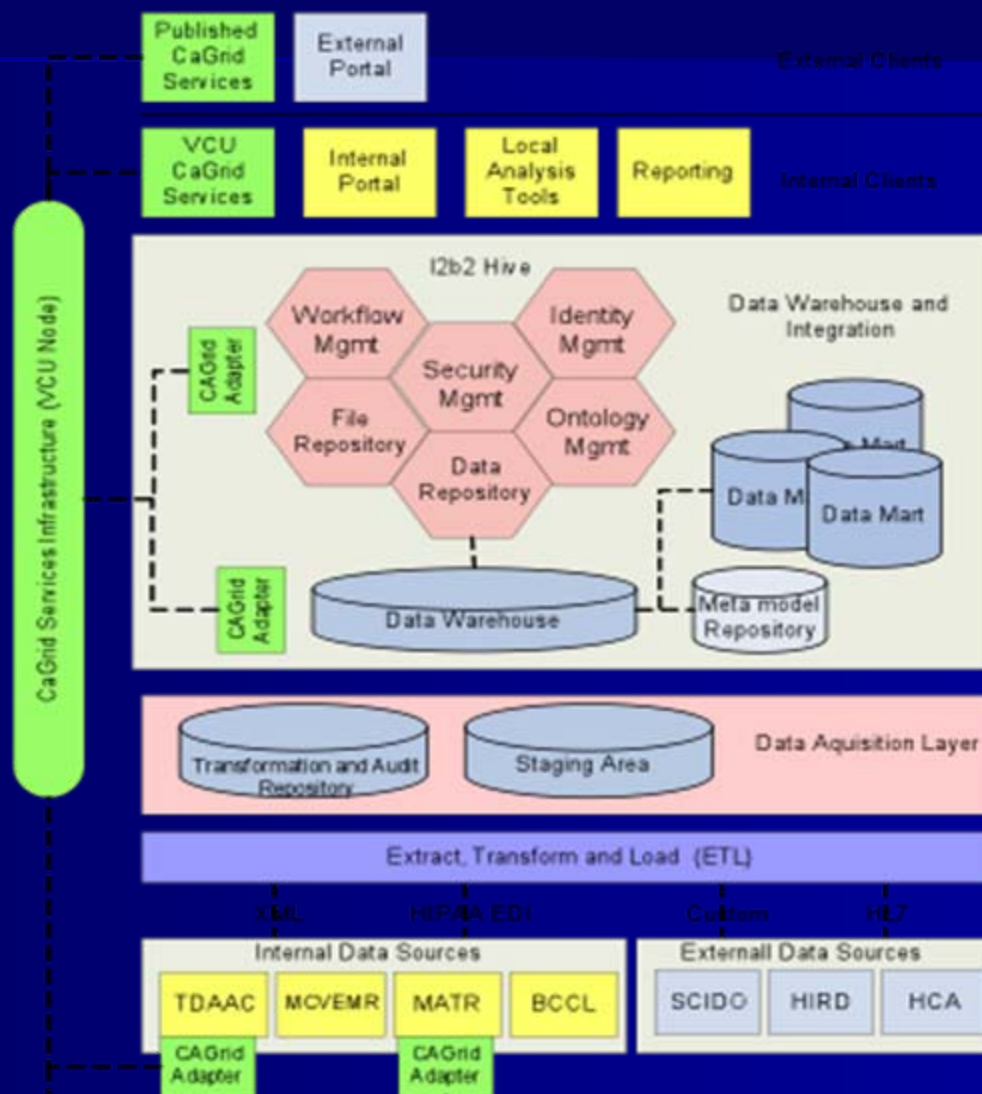
Bioinformatics	Medical Informatics	
<p>Systems and Resources</p> <ul style="list-style-type: none"> •Center for Biologic Complexity •Center for High Performance Computing •Bioinformatics & Computational Biology Support Core •Genomics, Proteomics, Transcriptomics Core •Nucleic Acid Research Facilities •Microarray Core •Gene Sythesis Core 	<p>Data and Systems Support</p> <ul style="list-style-type: none"> • Automated Clinical Extraction (ACE) <ul style="list-style-type: none"> •Create disease specific registries and clinical annotation of cases • Clinical Trials Eligibility DB (CTED) <ul style="list-style-type: none"> •Automated eligibility assessment of All patients in scheduling system • Tissue and Data Acquisition (TDAAC) & Analysis Core <ul style="list-style-type: none"> •for capture of tissue fluids, patient consenting and complete clinical Annotation 	<p>Office of Clinical Translation</p> <ul style="list-style-type: none"> • Clinical & Informatics Laboratory for assessing methods of implementation And dissemination to clinical care • Decision Support and Implementation of Evidence-Based Medical Practice



<p>Biostatistics Data Management & Services Core</p> <ul style="list-style-type: none"> • Provide data management services for investigators <ul style="list-style-type: none"> •SOPs for data acquisition, DB development, QA and storage • Oversight of data collection •Focusing data collection for specific research needs • Investigator support in <ul style="list-style-type: none"> • oversight of data base design, data to be collected, data storage and analysis 	<p>VCU Computing and Communications/Technology Service</p> <ul style="list-style-type: none"> • Provide server space and maintenance (software updates, security, backups, HIPPA-compliance) • Provide high level support for DB2, Oracle, and SQL server Supporting 'back-end' users- technicians for high-end problems • Provision for rapid access and short term technical temp services to support grant/research for data management administrators and analysts
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- What about database support and informatics?

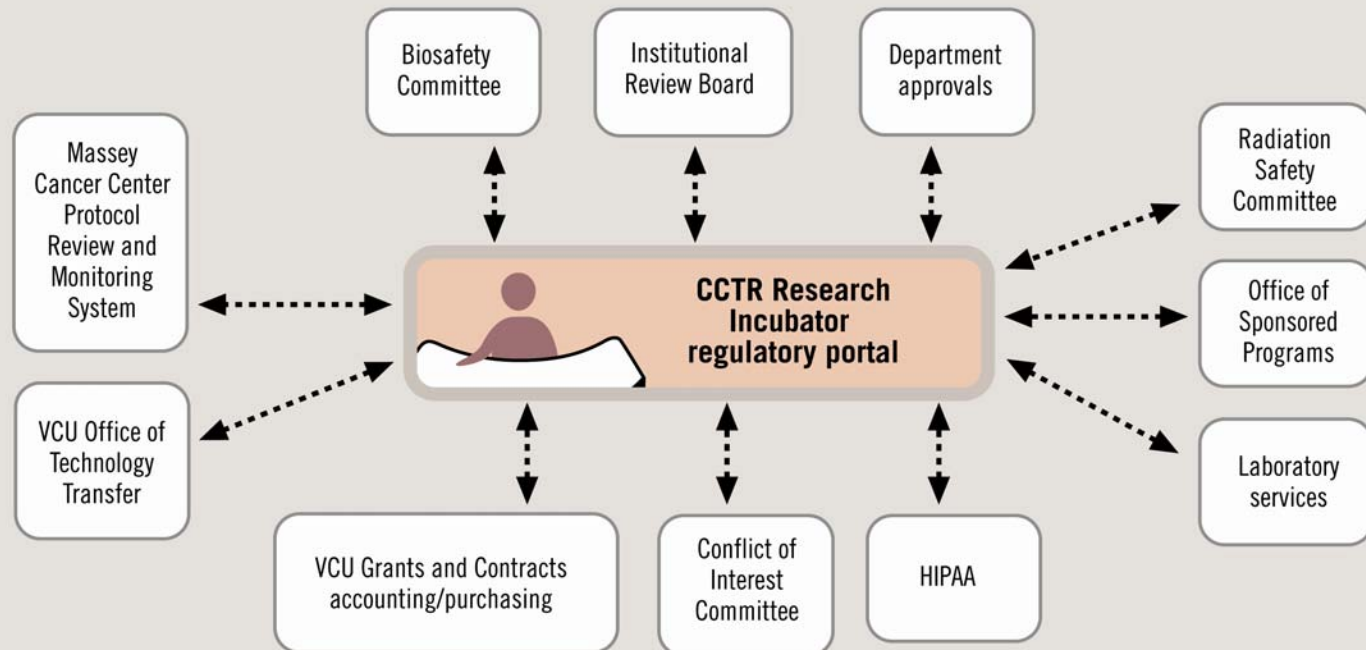
VCU Biomedical Informatics



Methods and Resources Needed

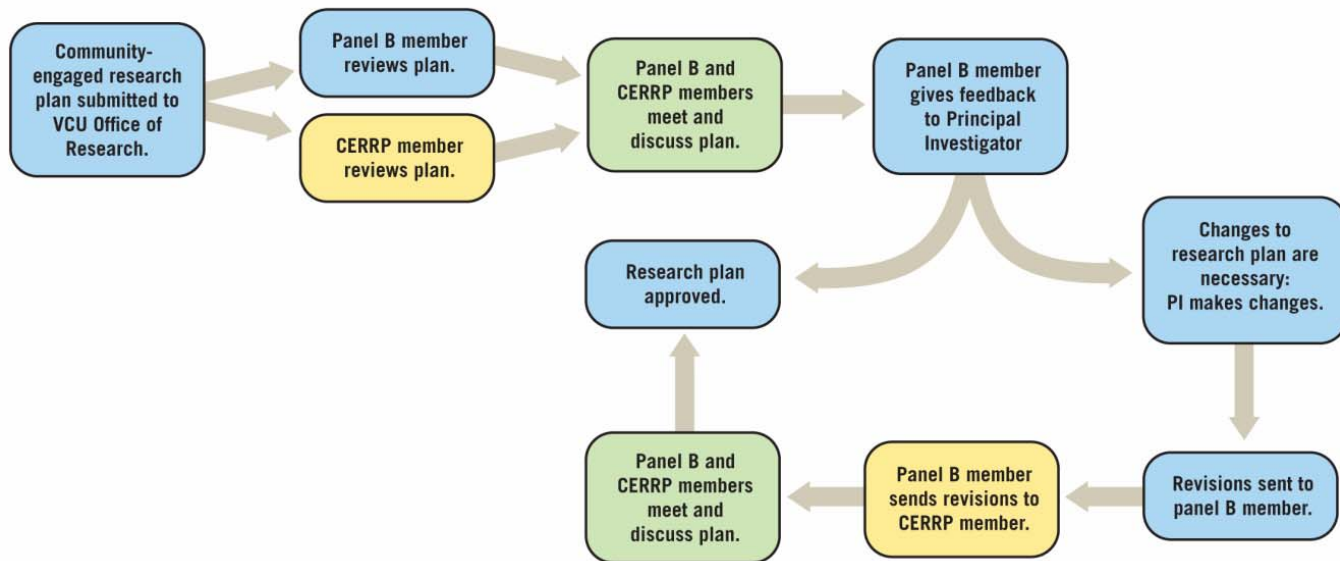
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Regulatory knowledge and support



Community-Engaged Research Review Panel process

● University ● University/community interface ● Community



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>

FINDING FUNDING

Ann Nichols-Casebolt, Ph.D.

Interim Associate Vice President for
Research Development

Office of the Vice President for Research

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>

Narrowing the Search

- **SPIN (Sponsored Programs Information Network)** – information on current national and international, government and private funding sources
- **SMARTS (SPIN Matching And Research Transmittal Service)** – automated daily alerts of funding opportunities that match keywords entered into your GENIUS profile
- **GENIUS (Global Expertise Network for Industry, Universities and Scholars)** – Houses profiles of investigators

Industry funding as an option

- VCU Office of Industry Partnerships
www.research.vcu.edu/oip/index.htm
- Dr. Michael Katz, Director
(mekatz@vcu.edu)

Getting help

- NIH grantwriting workshops
- Visit Office of Research website & click "Resources"
www.research.vcu.edu
- Library training
- Find a mentor
- Talk to people at lunch today!

Now What?

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

- Susan Robb CRA; Director, Sponsored Programs Administration

Electronic Submission

- <http://era.nih.gov/ElectronicReceipt/process.htm>

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)



After Submission to Funding Agency

- Submit protocol to
 - IRB/IACUC

<http://www.research.vcu.edu/orsp/index.htm>

- GCRC

<http://www.vcuhealth.org/crc/>

Other

Conclusion

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

Questions ?

Division of Animal Resources website

<http://www.research.vcu.edu/dar/index.htm>

Bobby Collins, DVM

Attending Veterinarian and Director of DAR

Telephone: (804) 828-9837

brcollins@vcu.edu

Methods and Resources Needed

- How do I measure SREBP ?
- How do I modulate expression of SREBP?
- How do I measure insulin resistance in a mouse?
- Where do I get the lab determinations done?
- What is the primary endpoint of this study?
- Where can I do this study ?
- **Where will the animals come from ?**
- What do I need to do to get approval for animal research?

Wild-type mice or other animals

Purchase from various vendors
(through DAR)

Genetically engineered mice

Purchase from JAX or other vendor
(through DAR)

- Obtain from investigator at another institution
(import coordinated by DAR)
- Develop new lines of mice
(VCU Transgenic/Knock-out Mouse Core)

Methods and Resources Needed

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Institutional Animal Care and Use Committee (IACUC)

<http://www.research.vcu.edu/iacuc/index.htm>

Research Training.org

- Occupational Health and Safety Program
for Animal Handlers

<http://www.research.vcu.edu/forms/iacuc.htm>

- Describe all procedures to be performed
- Justify the use of animals, species, and total number of
animals to be used

NIH Vertebrate Animals Section

<http://grants1.nih.gov/grants/funding/phs398/phs398.html>

Section F: Vertebrate Animals
Section I: Resource Sharing -
Sharing Model Organisms