

# Getting Started In Research on the MCV Campus

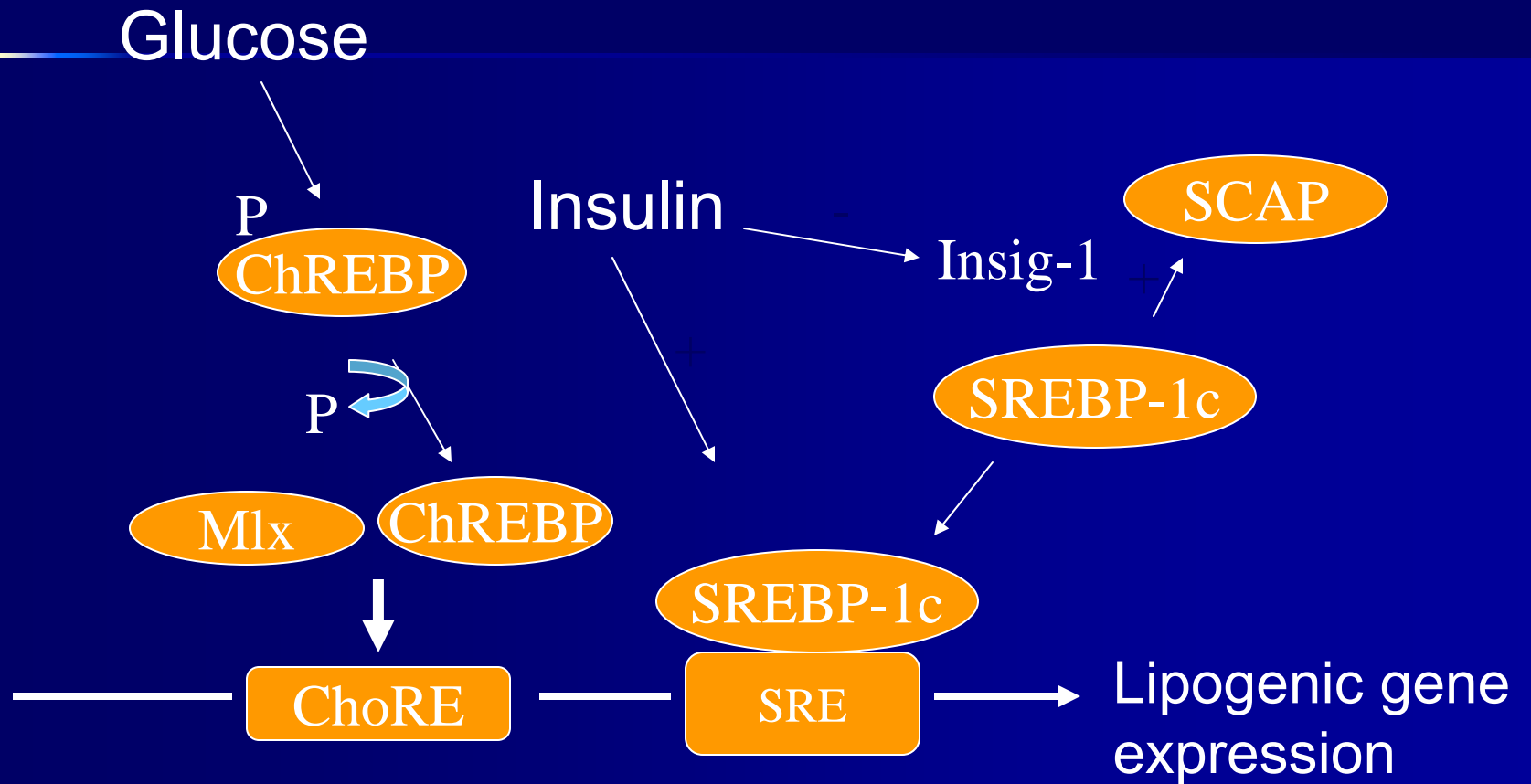
John N Clore MD  
Professor of Medicine and  
Associate Vice President for Clinical Research  
Director, CCTR



# 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**  
**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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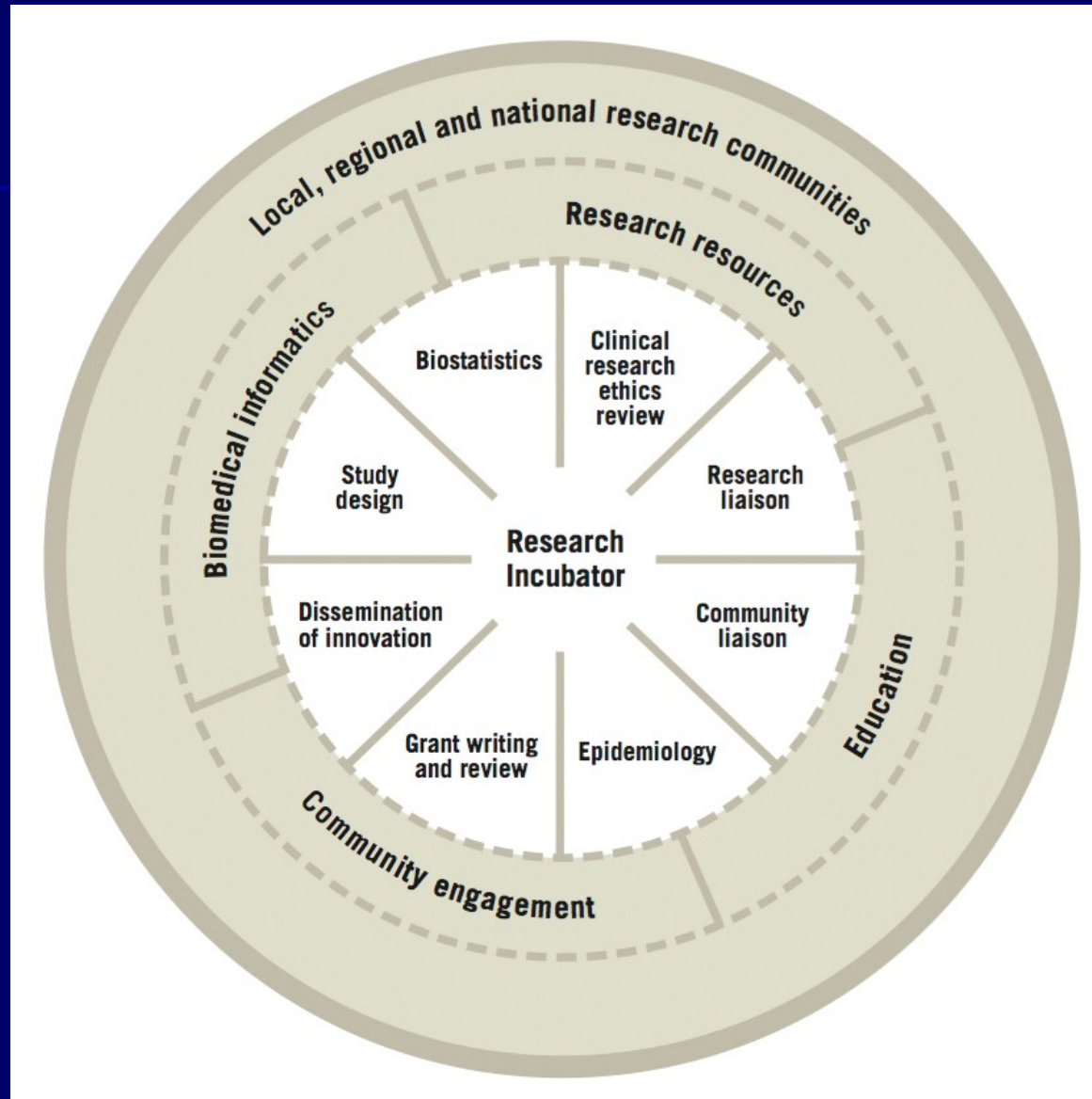
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# Center for Clinical and Translational Research 1200 E Clay St

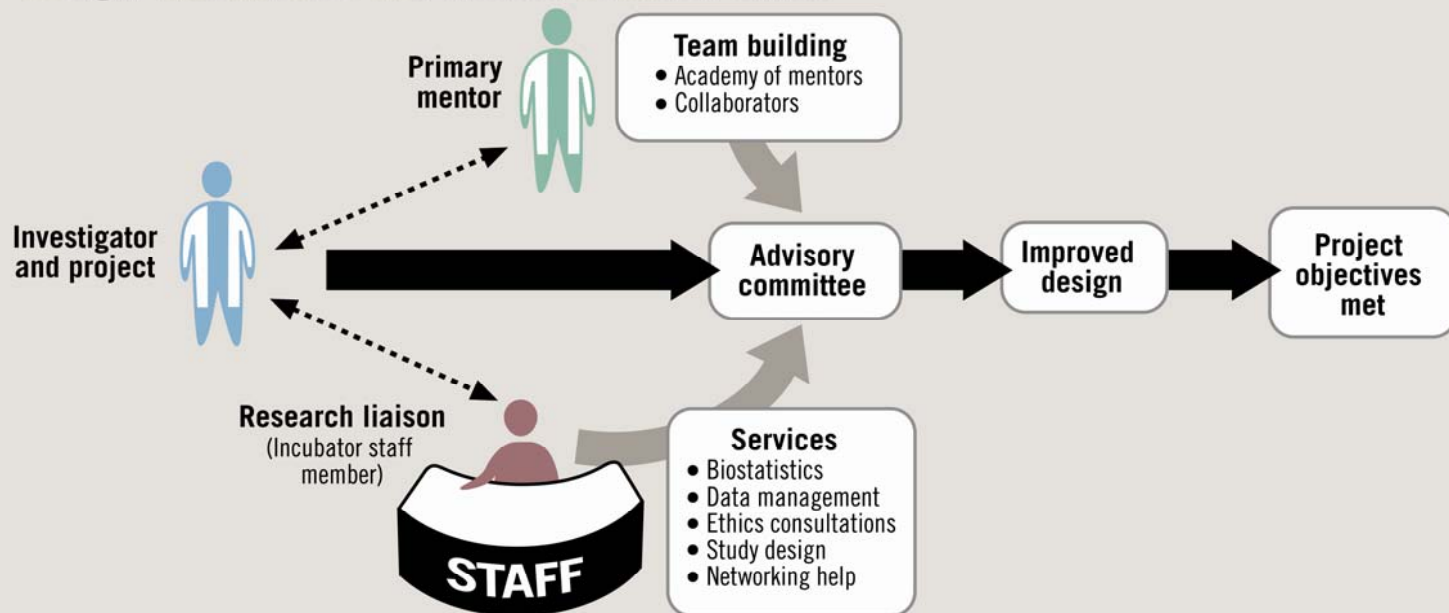
- [www.cctr.vcu.edu](http://www.cctr.vcu.edu)



# Research Incubator/CCTR

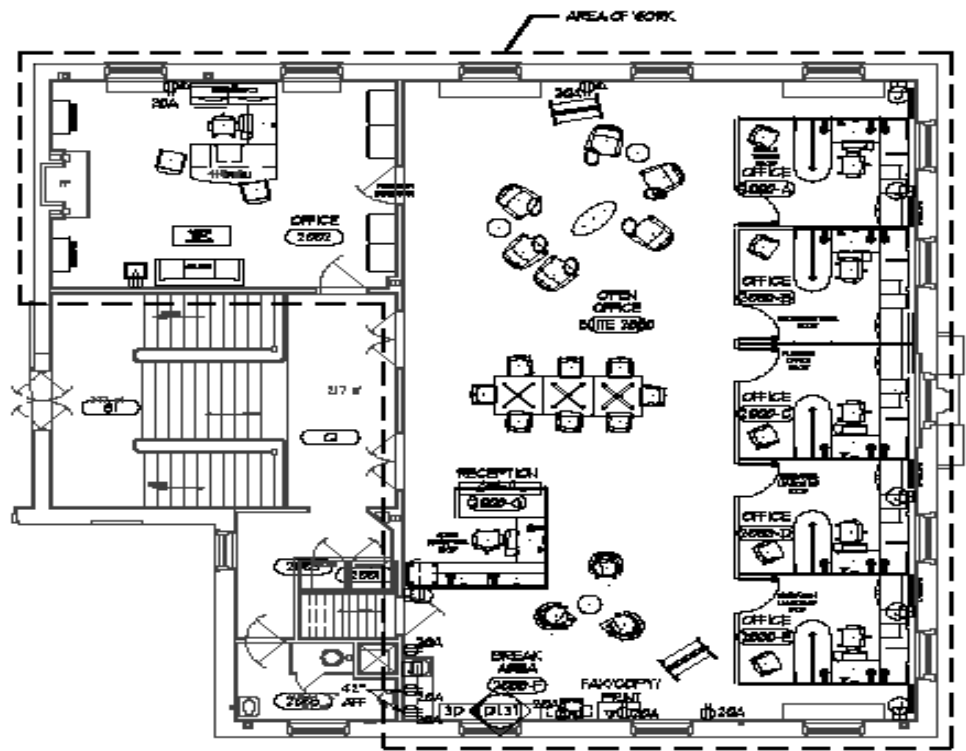


## Design, biostatistics and clinical research ethics





# Center for Clinical and Translational Research 1200 E Clay St



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**

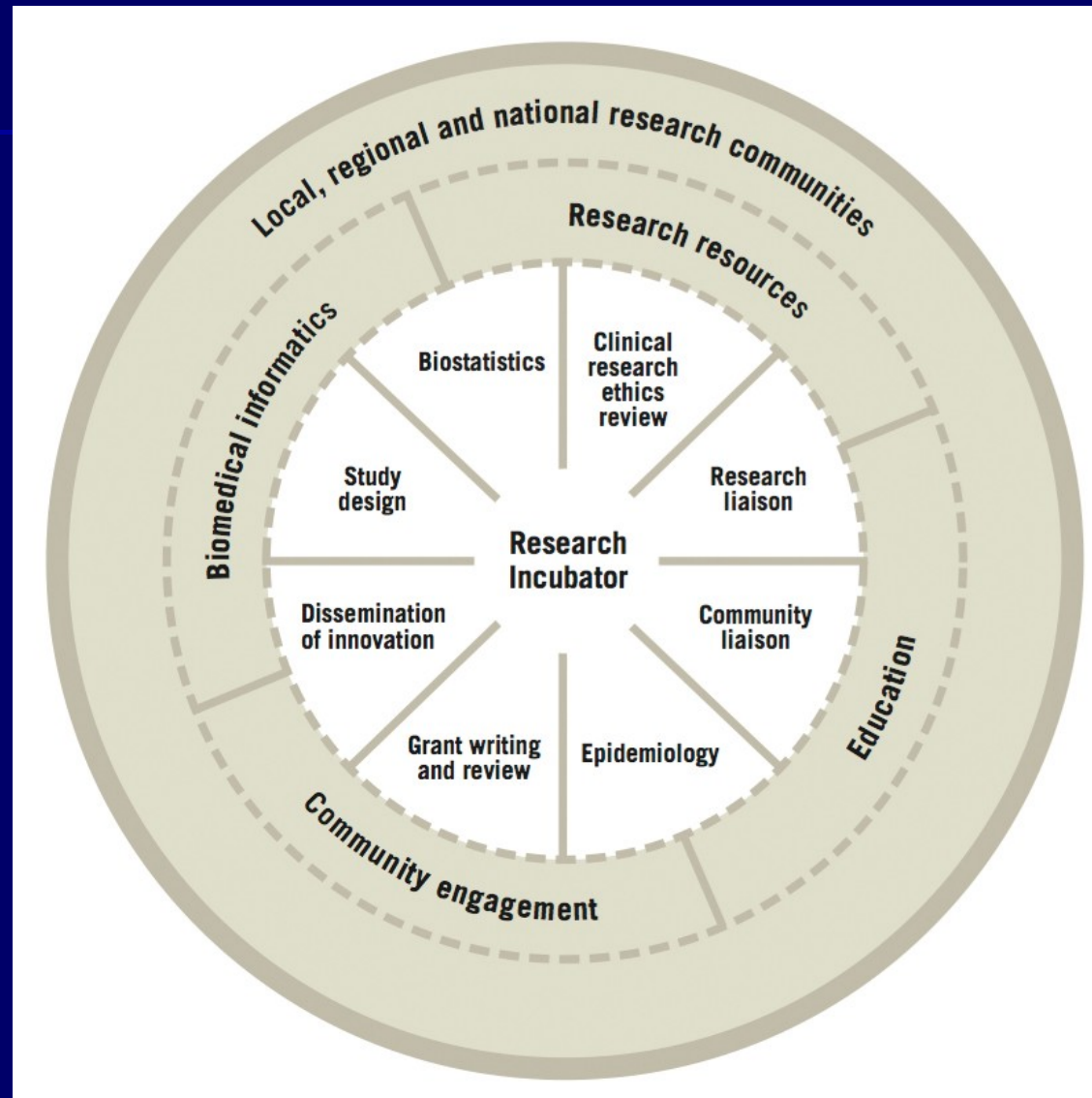
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**5A**

D191

# Research Incubator/CCTR



# Research Resources

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

# GCRC – North Hospital 8<sup>th</sup> Floor



# Research Resources

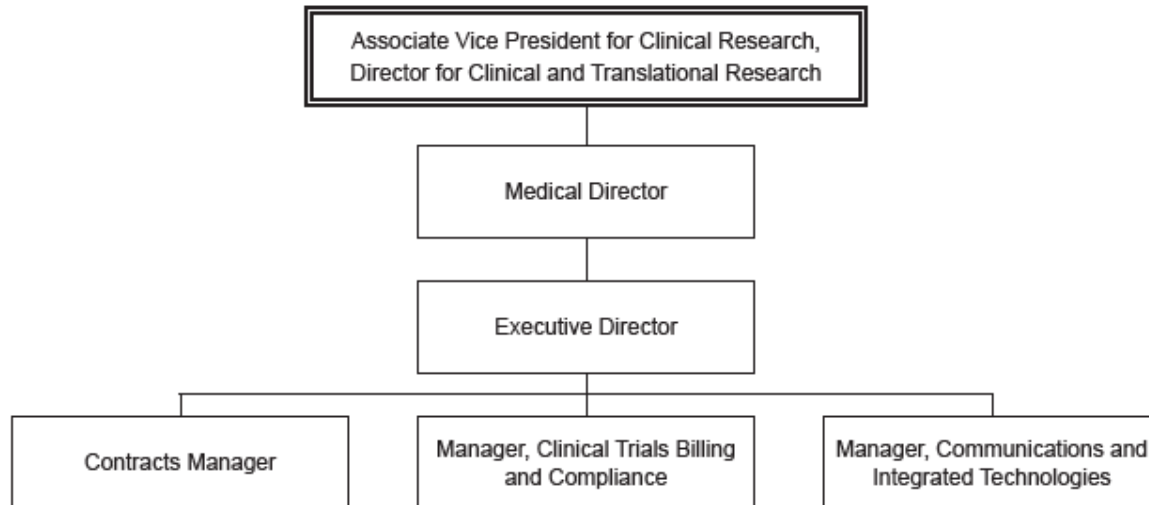
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# Clinical Trials Office

**VCU** Health Sciences

Virginia Commonwealth University

Clinical Trials Office

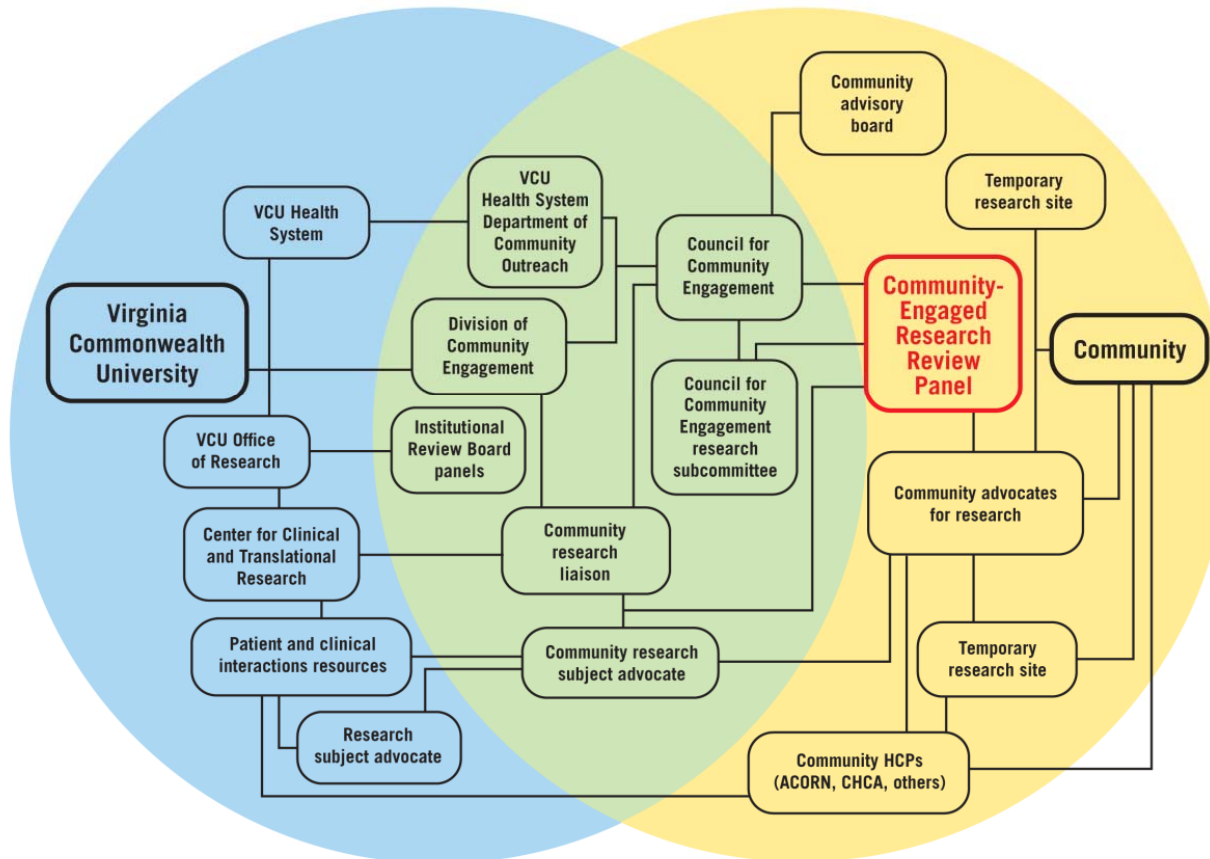


# Specific Aims

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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Richmond, Va.

University colleges and schools

Web People

Search

Go

# VCU Medical Center

Virginia Commonwealth University

Frequently Asked Questions

Glossary

Privacy/HIPAA

Resources

Find Clinical Trials at VCU

## Clinical Trials at VCU

*Every Day, A New Discovery.*

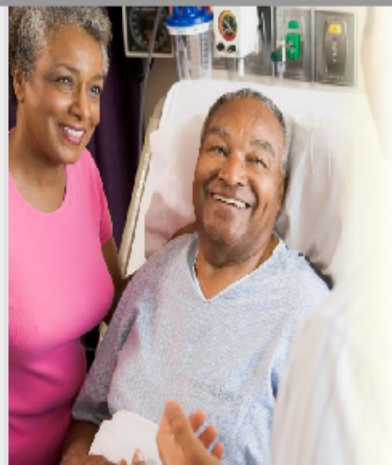
[Frequently Asked Questions](#)  
[Glossary](#)  
[Privacy/HIPAA](#)  
[Resources](#)  
[Find Clinical Trials at VCU](#)

[Feedback](#)

### Attention

Please help us keep our patients and you healthy during the season

- Wash your hands often with soap and water for at least 20 seconds.
- Do not visit if you are sick or have a fever, cough, sore throat, or other respiratory illness.
- Please do not have visitors if you are sick.



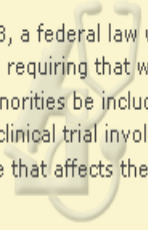
**Discovering**  
*through research*

**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.



### NEWS

[Resuscitation and Survival Rates from Out-of-Hospital Cardiac Arrest Nearly Double with Comprehensive Treatment Protocol](#)

[Researchers using excimer laser angioplasty to blast arterial blockages in heart and kidneys](#)

[Health Care Reform: Implications for Advancing](#)

### 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

# Methods and Resources Needed

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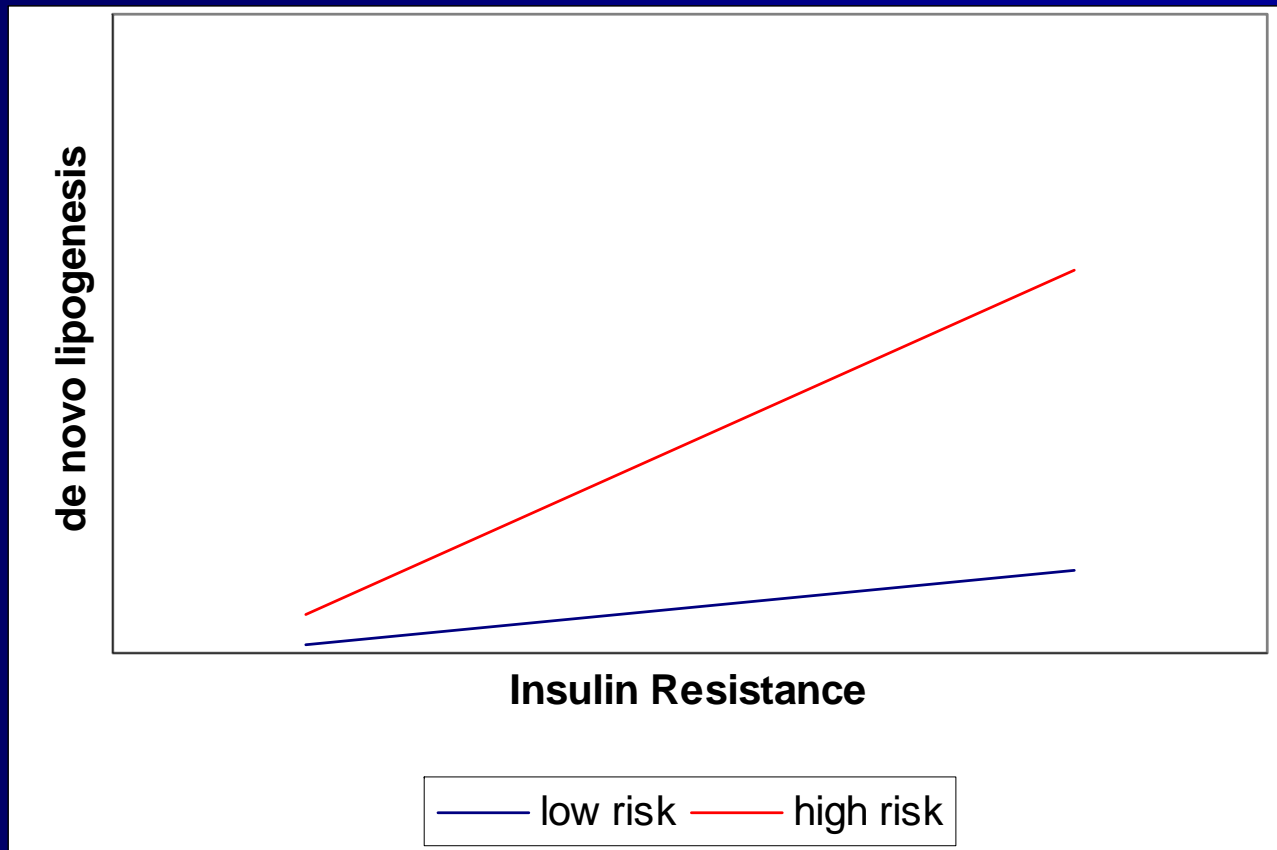
# Biostatistical Considerations

- 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



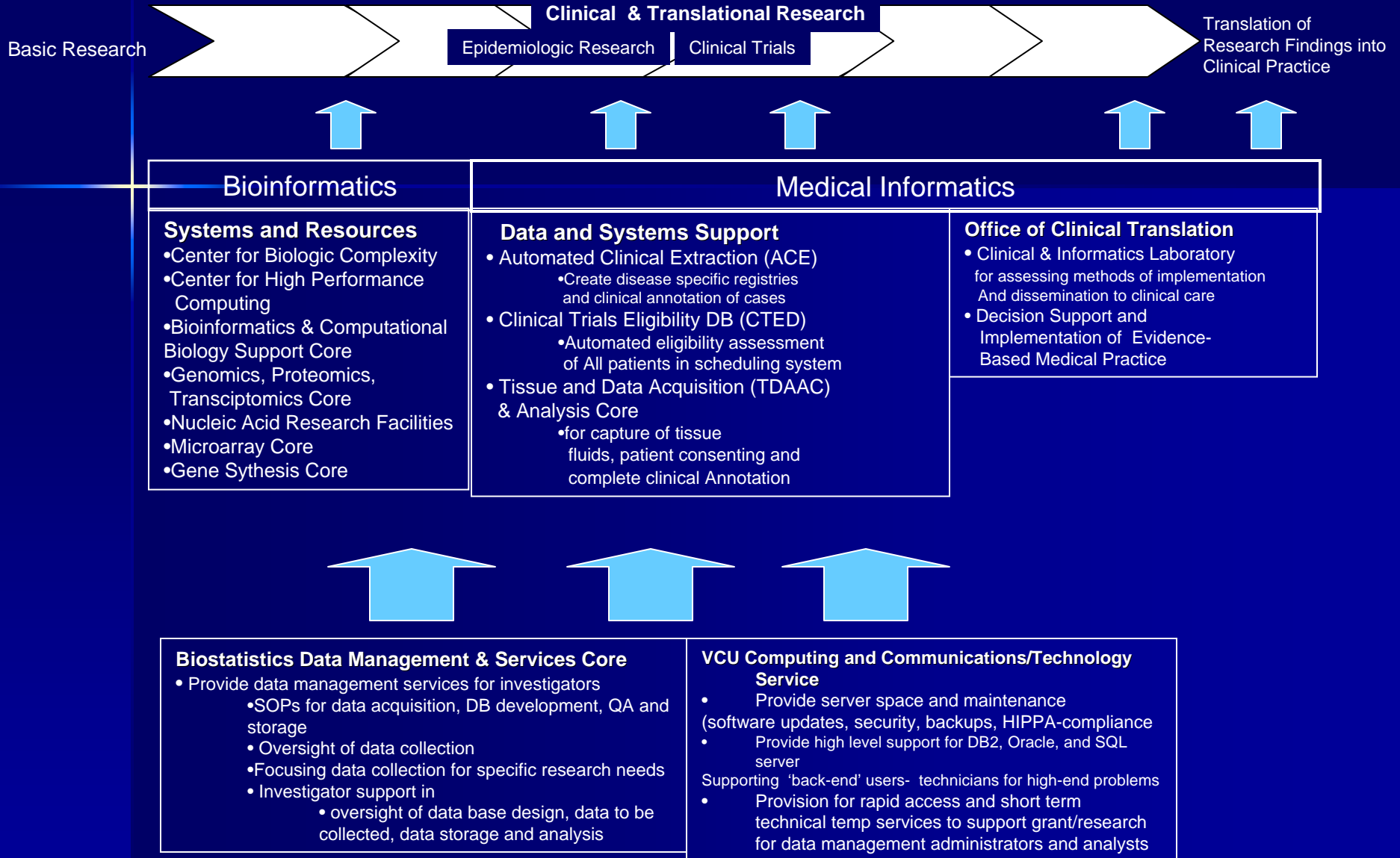
# Biostatistical Considerations

## 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

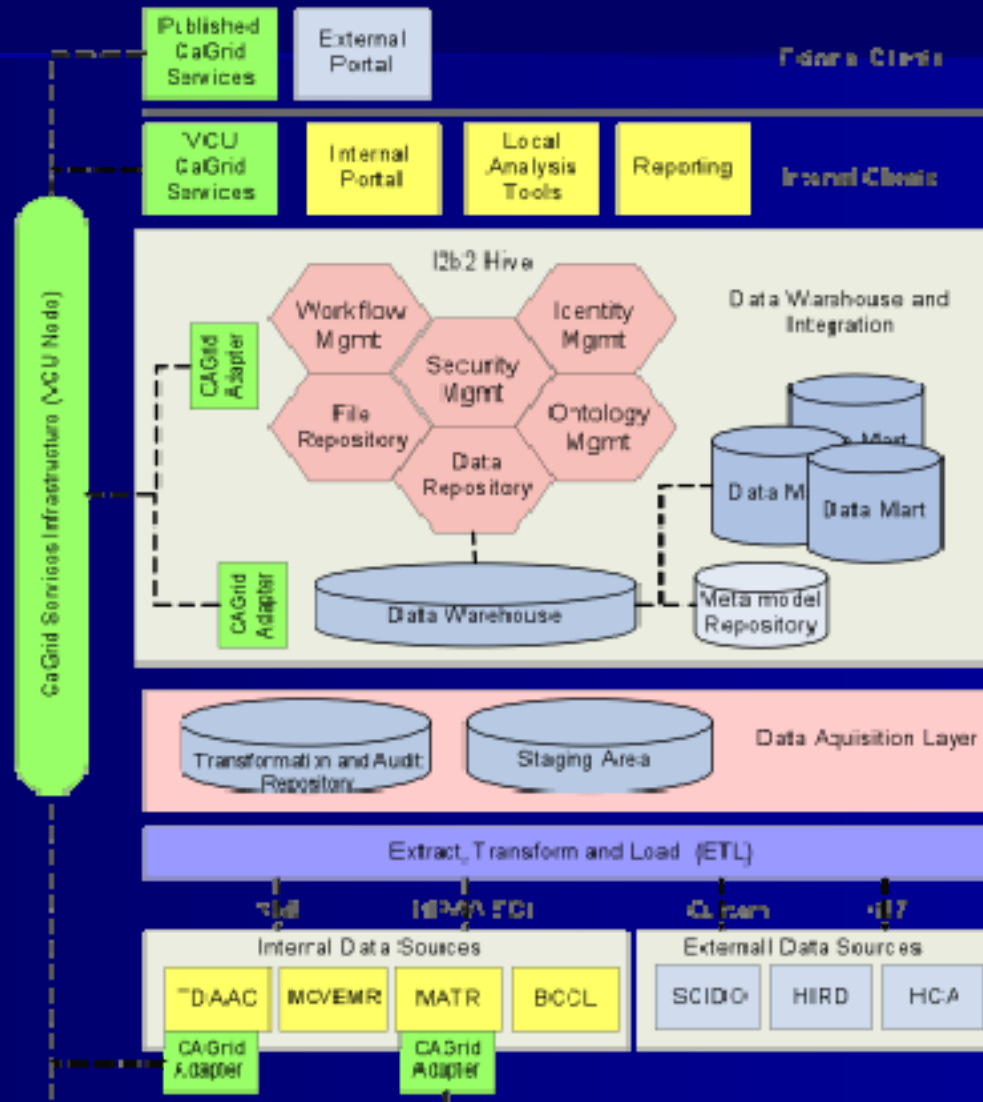


- What about database support and informatics?

- REDCap

Tim Aro- GCRC

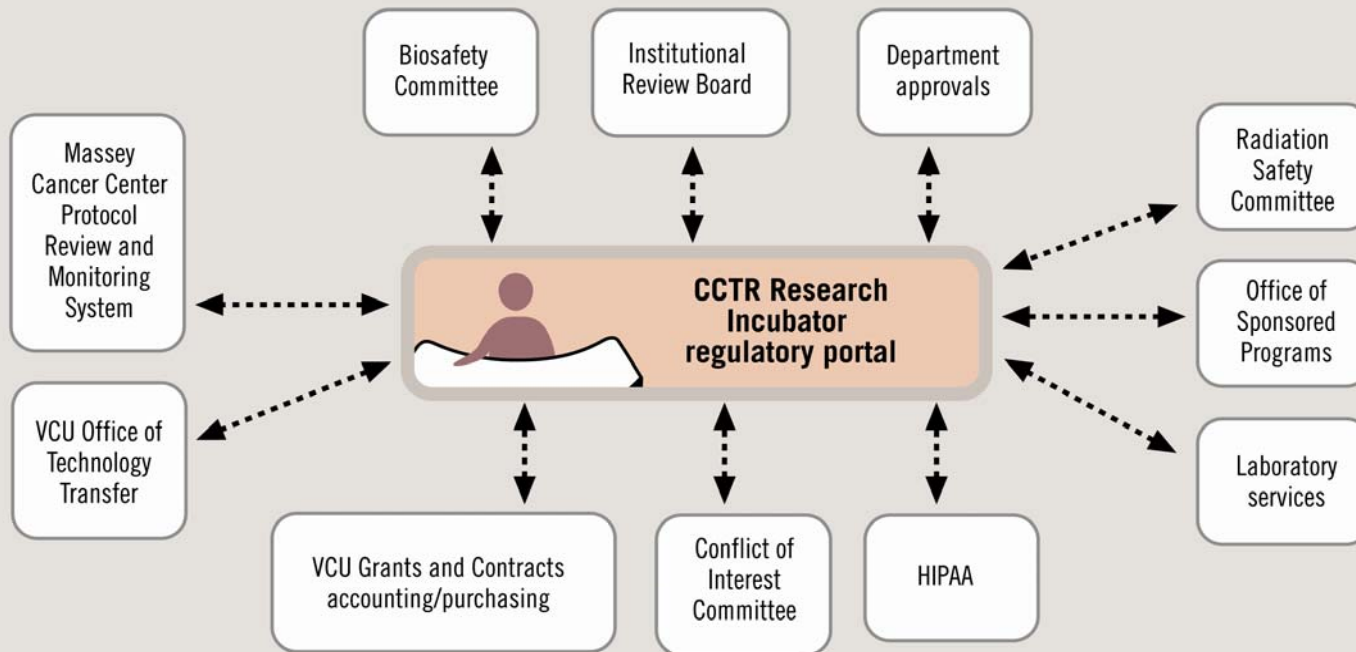
# VCU Biomedical Informatics



# Methods and Resources Needed

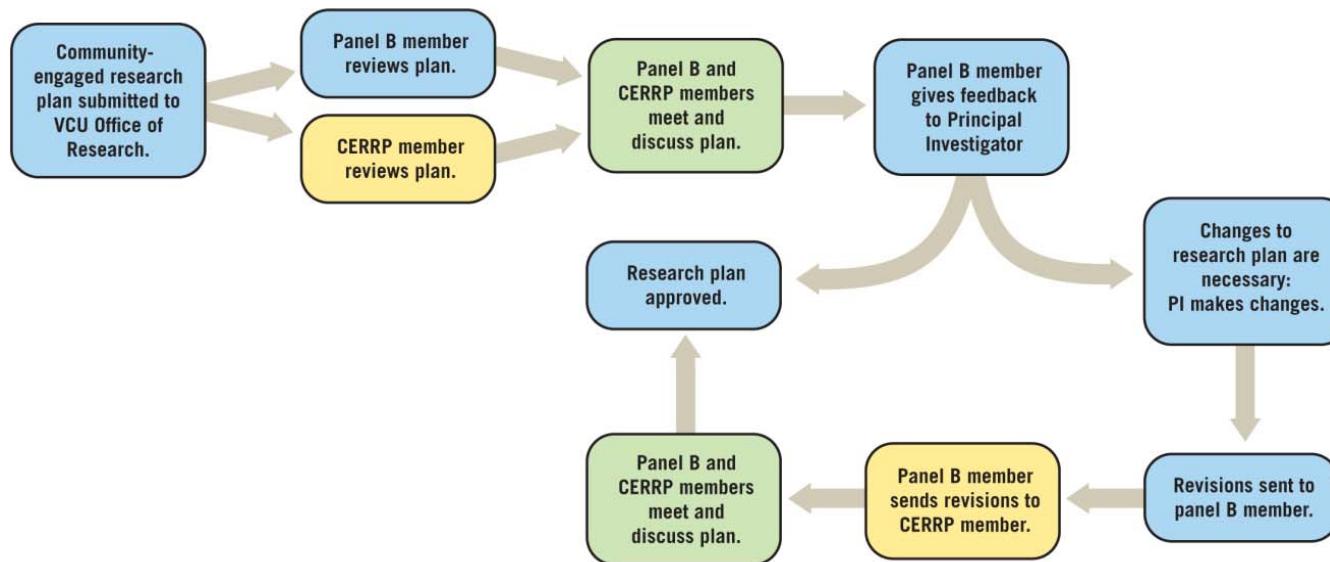
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## Regulatory knowledge and support



## 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>

# 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](http://www.grants.gov)
- NIH: funding opportunities at [www.nih.gov](http://www.nih.gov)
- NIH listserv: [listserv@list.nih.gov](mailto: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

- <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)



# Conclusion

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

Questions ?