Research: Why should I care and what should I know?

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Objectives

• Understand rationale for conducting research
• Know overall UNMC research goals
• Learn about local and regional research resources and where to go for questions about research resources
• Know about recent changes in research processes
Conflict of interest disclosure

Jennifer Larsen, M.D.
• Consultant: American Board of Internal Medicine, Endocrine Society/Endocrine Reviews Editorial Review Board

Chris Kratochvil, M.D.
• Consultant: DSMBs for Pfizer, Seaside, Otsuka, Neuren, NIH and FDA Advisory Committees. Theravance.
• Publishing: Oxford Press
• Research funding: Eli Lilly, Shire, Forest, NIH
What is research?

Systematic investigation to establish facts and reach new conclusions.

While IRB has its own definition of what is or is not research, research can be quite broad….
Translational Research

“Bench”

“Bedside”

“Community”
Other types to consider

- Epidemiology
- Personalized medicine
- Quality improvement/health outcomes
- Comparative effectiveness research (CER)
- Dissemination research
- Community-engaged/Community-based participatory research (CPBR)
- Educational research
- Technology development
- Bioterrorism (National Strategic Research Institute)
Why do research?

- Paradigm changing knowledge
- Improve health
- Reduce health care costs
- Fulfill training and maintenance of certification requirements
- Improve your professional future
- Expand unit revenue or provide new resources
- Enhance patient referrals to our system, regionally, nationally and globally
- Improve the economy of Nebraska
Research Awards

Millions of Dollars

Year Ending July

Based on first quarter projections

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UNMC Research Goals

- Grow funded research to $200 million
- Lead globally recognized research programs
- Improve the health of Nebraska
- Be an economic driver for Nebraska
UNMC Research Awards
by Sponsor

Millions of $

Year

2007 2008 2009 2010 2011 2012 2013 2014

Federal Pharma State Other
Internal Medicine Research Awards

By Sponsor

- Federal
- Pharma
- State
- Other

Millions of $

Year

2007 2008 2009 2010 2011 2012 2013 2014
Nebraska Advanced Biomedical Technology Innovation & Discovery Institute

- U-wide Collaboration
- Focus areas: robotics, health related devices and tools, biomarkers, biologics and nanomedicines, informatics
National Strategic Research Institute (NSRI) www.nsri.nebraska.edu

A University Affiliated Research Center (UARC) at the University of Nebraska

Capabilities and Services for Defense-related Research

Dec 6, 2012
NSRI Core Competencies

**Nuclear detection and forensics**
- Standoff Detection, Radiation Analysis

**Space, cyber and telecommunications law**
- Space Traffic Management, Space Asset Security, Legal Protocol Development

**Consequence management**
- Decision support, disaster mitigation, hazard modeling, Biosurveillance, Diagnostics, Decontamination

**Detection of chemical and biological weapons**

**Passive medical defense against weapons of mass destruction**
- Medical Countermeasures, Vaccine Development, Antidotes, Human Performance
Paula Turpen, PhD

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- Proteomics and Systems Biology
- Cell and Tissue Analysis
- Cell and Tissue Imaging with super-resolution microscopy
- Genomics with ‘next generation’ DNA sequencing, epigenomics, microarray and single cell genomics
- Animal models, behavior, and physiology
- Bioinformatics and Systems Biology
- Human and Animal Bioimaging with magnetoencephalography (MEG) for human studies
New NIH Biosketch format

• Effective date: **May 25, 2015**
• New Community in Science replaces Select Peer Review publications SF424 R&R Application and Electronic Submission Information forms
• Includes option to link to full publication list in a public database such as SciENcv (Science Experts Network Curriculum Vitae)
• VCR office & SPA will host workshops to introduce the new biosketch and tools
UNMC Research Handbook: guide to research policies, resources, procedures

www.unmc.edu/vcr/about/research-handbook-web.pdf

Provide any comments, edits, suggestions to Linda Wilkie
lwilkie@unmc.edu
Other questions?

• Vice Chancellor for Research website [www.unmc.edu/vcr](http://www.unmc.edu/vcr)
• Call VCR Office
• Clinical research resources: Clinical Research Center
So you want to conduct a clinical trial....
“It’s time we face reality, my friends. ...We’re not exactly rocket scientists.”
Steps to Consider

- **Overall processes and resources:** Research Handbook, VCR web site, Clinical Research Center
- **Feasibility:** assessing your patient population
- **Developing a study design:** sample size analysis and support
- **Funding for preliminary data:** local resources
- **Developing a research database** (REDCAP)
- **Clinical research support services** including research pharmacy consultation or support, developing a budget
- **IRB application and review**
- **Recruitment resources**
- **Research Billing**
Feasibility: Electronic Health Record Access Core

- Purnima Guda, PhD, Director
- Application: [http://www.unmc.edu/cctr/ehr-services.htm](http://www.unmc.edu/cctr/ehr-services.htm)
- Provides access to EHR Data
  - Feasibility for clinical trials
  - Eligible subjects for recruitment to clinical trials
  - Retrospective data sets
  - Quality improvement projects
- Requests for identified data: IRB approval
"Meaningless statistics were up one-point-five per cent this month over last month."
CCORDA: Sample size analysis, study design, and biostatistical plan

Center for Collaboration on Research Design and Analysis

www.unmc.edu/publichealth/centers/ccorda

- Clinical Trial Design
- Research Database Development
- Data Safety Monitoring
- Biostatistics analysis
- Epidemiology
- Health Services Research
- Medical Geography
- Medical Economics
- Access to public databases

CCORDA Director
Fang Yu, PhD
fanyu@unmc.edu
Preliminary data:
Consider Nebraska Biobank: a U-wide resource

Research repository of annotated human DNA and serum
(30,000 samples)
Chris Kratochvil, MD  ckratoch@unmc.edu
On-line Application
Funding Opportunities

Office of Vice Chancellor for Research Resources for Researchers

About Us | Find an Expert | Funding | Research IT | Cores and Services | Research Policies | Education

UNMC > VCR > Funding

Funding Opportunities

- SciVal Funding
  - Internal Funding Opportunities
  - Catalog of External Funding Opportunities
  - National Strategic Research Institute (NSRI)
  - Intellectual Property Assistance
  - UNeMed Clinical Trials
  - Sponsored Programs Administration
  - Grant Writing Support

Rapid Response Opportunities

Rapid response opportunities have an internal deadline under 60 days.

- 2015 NRI Faculty Research Proposals
- 2015 Nebraska Biobank RFA
- DoD Funding Opportunities

Quick Funding Search

SciVal FUNDING
NIH Weekly Funding Announcements
UNL Weekly Funding Announcements
VA Funding Announcements

Download Quick Reference Guides for:

- Industry Sponsored Trials & Registries
- Basic Science
Regional funding Opportunities

• **Nebraska Research Initiative (NRI) collaborative grants:** $100K for new collaborations focused on economic development

• **Ittner Pediatric Fund:** $40K for pediatric diseases

• **Nebraska Banker’s Fund:** small clinical equipment

• **NRI resource development:** shared instrument equipment/resource development

• **Research Support Fund:** write off of Nebraska Medicine-based expenses after peer review

CCTR website [http://ctsa.unmc.edu](http://ctsa.unmc.edu)
Funding Opportunities
SciVal: searchable database 4,000 public/private funding sources

Set Personal Preferences and Alerts
Partnering with Industry

• Contact to develop a new idea into a new technology including available resources

• Contact to participate in a multicenter commercial clinical trial

• Contracting & budgeting
Research database? contact Research Information Technology Office

Director: Ashok Mudgapalli, PhD

- **Research Electronic Data Capture:** REDCap (>300 protocols)
- Other support for research data storage solutions, implementation of new technologies, and connecting data sources
- [http://www.unmc.edu/vcr/rito.htm](http://www.unmc.edu/vcr/rito.htm)
Clinical Research Center: a resource center for clinical research

LuAnn Larson, RN, BSN, CCRP, Nurse Manager

- 9 exam rooms
- 1 dental/ENT exam room
- Lab
- Work room
- Phlebotomy area
- Waiting room
- Reception area
Clinical Research Center: One-Stop Shop

Peggy Heires, RD- “Clinical Research Navigator”

• Consultation on clinical research policies & resources
• Research procedures (examples):
  • Phlebotomy, infusions, blood pressure monitoring.
  • Surveys and other patient assessments
  • Treadmill testing
• Laboratory support for processing samples
• Clinical Space
• Assistance with budget development & regulatory documents
• Finding research pricing (75% reduction)
• Coverage Analysis: Katie Penas, MHA, RT
Nebraska Medicine
Investigational Pharmacy

Jon Beck, PharmD
Coordinator, Investigational Drug Service, Nebraska Medicine

Erin J. Iselin, Pharm.D.
Research Pharmacist

Heather Kloppenborg, B.S.
Research Pharmacy Technician

- Protocol Assistance
- Regulatory
- Documentation
- Dispensing
- Drug Information
- Preceptor
- Inventory Control
- Drug information, consultation and review, Pharmacy & Therapeutics (P&T)
IRB updates

- Electronic IRB application
- Can reference full protocol for sponsored studies
  - background, inclusion/exclusion, methods, stats, references, etc
- Discussion regarding merging Cancer SRC application
- Central IRB possible for NIH & ultimately commercial protocols
- Questions: ask the IRB
Clinical Trials Recruitment

http://net.unmc.edu/ctsearch/index_unmc.php

- Clinical Trials Database
- Patient Lists: P. Guda, PhD
- One Chart Best Practice Alerts: Courtney Kennedy RN, MSN
- Conditions of Treatment Form: recruitment option COMING SOON!
One Chart EHR & Research

Courtney Kennedy, RN, MSN
One Chart Technical Lead

- Research order sets
- Enters studies into One Chart
- Develops and implements new One Chart features
- Trains study coordinators and investigators
Research Billing

Cassie Cruz-Montes – Research Billing Sr. Associate
  – study matrices, study audits, help with billing
  – resource for training
  – questions
  – problem-solving, and liaison to billing

Change in research billing flow

Coordinators will still
  – Create comprehensive matrix
  – Enter patient visit data within 24 hours
  – Scan the consent into One Chart within 24 h
New resources

- **Quarterly Coordinator Meetings/Newsletter**
- **Nebraska Joint Public Health Data Center:**
  Nebraska’s public health data hosted by College of Public Health
- **PCORNet:** PCORI-funded multi-state electronic health record dataset available for comparative effectiveness research
- **UNL Research Data Center:** US Census data center allowing secure access to public health data sets (e.g., NHANES)
- **Primary Care Practice Based Research Network:**
  rural and urban primary care practices to trial new approaches to common health problems
Eventually, Billy came to dread his father’s lectures over all other forms of punishment.