Getting Started with your Research: Identifying Resources and Developing Strategies

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Objectives

- To provide some basic information to starting a research project.
- To highlight potential research resources using UNMC as an example.
 - This information is primarily aimed at HUMAN research but applies to basic science studies as well.
 - Remember as PI, you have primary responsibility to your research subject/participants and to the proper execution of your study (not study coordinator or co-investigators).



1. First Step: Having an idea



Define your subject area or interest.

** What is the hypothesis? **



2. Decide on a Research Focus

Write a literature review on your topic

- Create reference list
- Ensures complete and current knowledge of literature
- Identify literature voids or poor quality
- Is there a knowledge gap or not?



3. Search the Literature



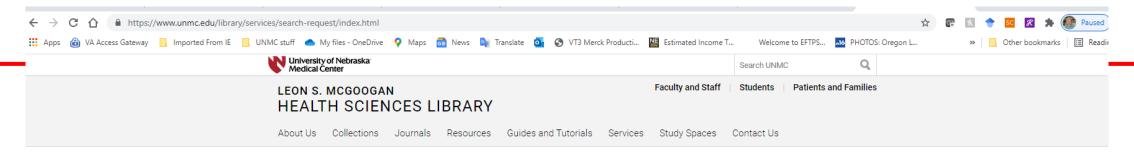
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- https://scholar.google.com/
- https://www.scopus.com/home.uri
- https://www.webofscience.com/wos/bioabs/basicsearch
- https://www.refseek.com/
- Institutional librarian may provide searches (free of charge) or assist in scoping reviews (not usually free).



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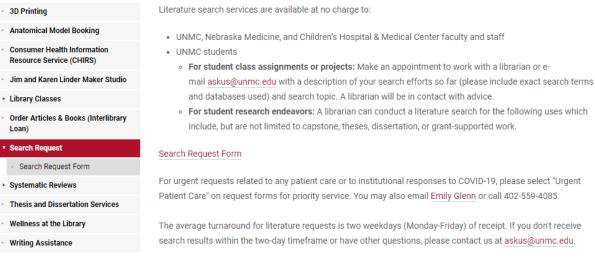


UNMC Library Services



UNMC > Library > Services > Search Request

Search Request



For urgent requests related to any patient care or to institutional responses to COVID-19, please select "Urgent Patient Care" on request forms for priority service. You may also email Emily Glenn or call 402-559-4085.

The average turnaround for literature requests is two weekdays (Monday-Friday) of receipt. If you don't receive search results within the two-day timeframe or have other questions, please contact us at askus@unmc.edu.

Systematic Review Search Form

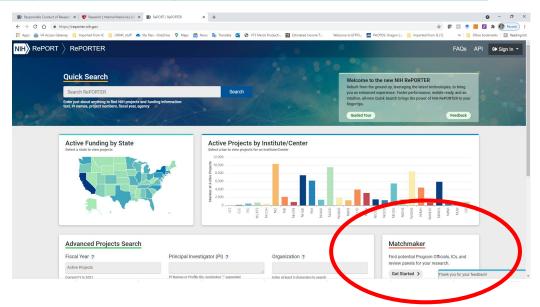
If you are considering a systematic review literature search, please review our Systematic Reviews guide and Description of Services. Systematic Review searching is only available to UNMC and affiliated partners.

Nebraska residents needing health information for their or their family's health may request service at no charge from (CHIRS), the Consumer Health Information Resource Service.



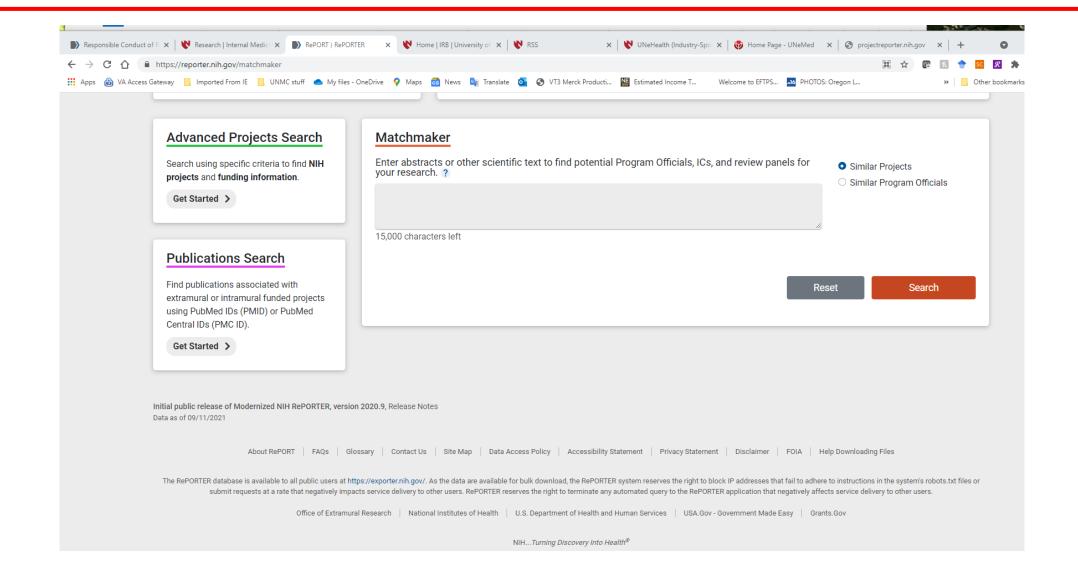
4. Make sure this isn't already being done

- Is there someone already doing this work that isn't published?
 - https://reporter.nih.gov/
 - https://reporter.nih.gov/matchmaker
 - https://wellcome.org/grant-funding/people-and-projects/grants-awarded
 - https://www.grantforward.com/index (institutional membership required)





MATCHMAKER





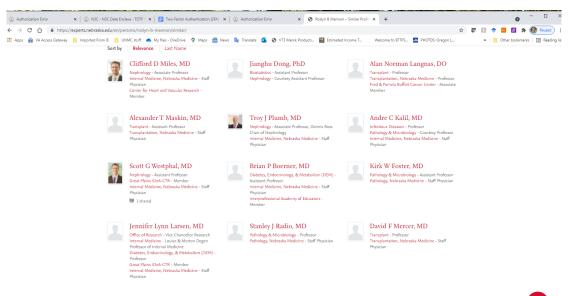
5. Speak/Meet/Hear the Experts

- Talk with your mentor
 - Prepare an "idea page" with your hypothesis, background and how you plan to study this question.
 - Make a figure of what you are trying to do!
- Attend meetings and listen to the topic areas of interest or visit posters
 - Ask questions

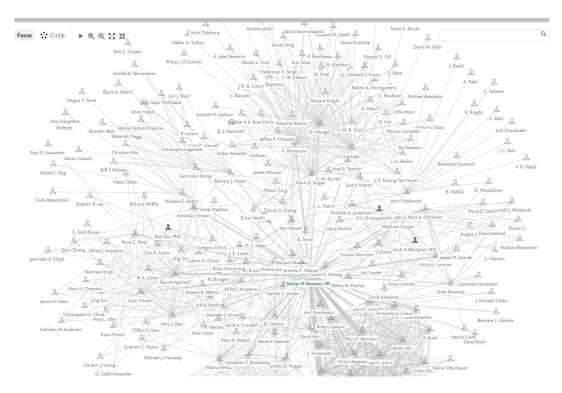


Research Nebraska

- https://experts.nebraska.edu/
- Opportunity to see who may serve as potential collaborators or mentors (or competitors).



2017 – present





6. Steps in Developing Your Program

- 1. Develop the logical sequence of future studies
- 2. Realistically evaluate likelihood of success
 - Identify collaborators attempting to create research team
 - Ideally research would be complimentary to collaborators
 - Identify population to insure successful conduct of your study
- 3. Evaluate your situation



6a. Evaluate your situation

- What is your experience level?
 - Beginner
 - Adv Beginner
 - Intermediate
 - Advanced
- Do you have institutional support?
 - Money
 - Space
 - People to help
 - Core resources
 - Protected time



Manuscripts

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6b. Key Issues In The Design Of Clinical Research Programs

- Define your hypothesis
 - Define your primary and secondary endpoints
- Create data collection tools
- Develop a database (this becomes your historical control)
 - Collect data in the rawest form
 - "Test" analyze your data early to identify any data collection problems
- Participate in biobanks or repositories
- Develop the logical sequence of future studies

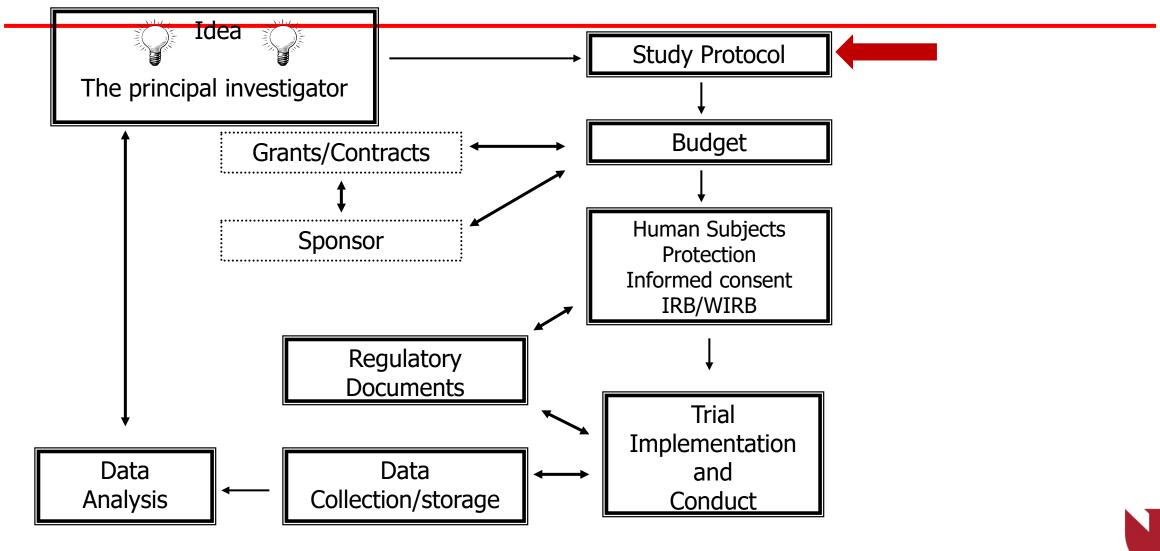


Consider....

- Most likely funding source
- Extent of support staff you need
- Who will manage the regulatory paperwork? Your budgets?
- Who will be screening and enrolling participants?



The Clinical Research Enterprise



Kidney and Transplant Research: Flexible Design (but big overhead)

Roslyn Mannon
Associate Chief of Nephrology, Research

Transplant and Nephrology Clinical Research

NIH Funded Industry Sponsored Multiple PI's Research Manager Kathleen Tinley BS

> UNMC Core Resources

Lab Investigation

Mechanistic investigations into acute and chronic injury

Mannon Lab

SOT Informatics N3C UNMC, VCU, UAB, Halifax



The People: Determine What You Need

- Regulatory manager
- Budget / account manager
- Research nurse(s) versus research coordinators
- Biostatistics
- Bioinformatics
- Bench lab personnel





7. Advancing your research focus

- Collect baseline data
 - Conduct retrospective review, quality improvement project, etc.
 - Test outcome variables, data collection tools, data analysis methods
 - Publish and present results EVERYWHERE
- 2. Design a **pilot study** to provide baseline data for continued research
- 3. Design a quality study
 - Apply all aspects of quality research such as
 - randomization, blinding, stratification
 - Remove questions of investigator bias



Answering Operational Questions

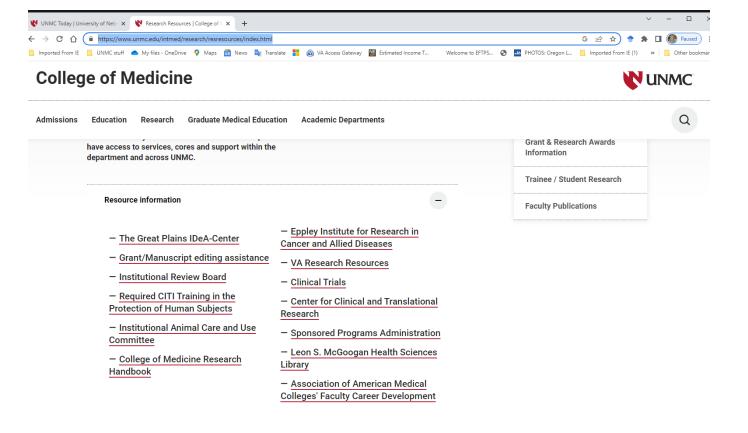
- Your mentor (s)
- Your division/department research manager
- Your division/department grant coordinator
- Peers and other faculty
- Associate/Assistant Vice Chair of Research
- CTR coursework
- VCR research website (chock full of info: https://www.unmc.edu/vcr/)



Resource Page (example, Dept Int Med UNMC)

• https://www.unmc.edu/intmed/research/resresources/index.

<u>html</u>





Assessing your Skill Sets

- Writing
 - Have I written an abstract?
 - Have I written a paper?
 - Have I written a grant?
- Presentation skills
- Research specific skills
 - Bench versus desktop
- Scope of work and need for collaborators
 - Research Nebraska is a good local start
 - Ask your mentor!



Different Modalities of Research Communication

Abstracts

- Brief presentation of your project with results that you intend to publish
- Typically, about 250 words, format based on meeting
- Posters: templates are available internally but important to follow the meeting guidelines.

Talks/presentations

- Do you need public speaking practice?
- Time limits: budget about 30sec-1min per slide
 - More complex slides with multiple panels need more
 - REHEARSE use timer (PowerPoint)
- Beginning, middle, ending and remember acknowledge funding sources and collaborators/key contributions

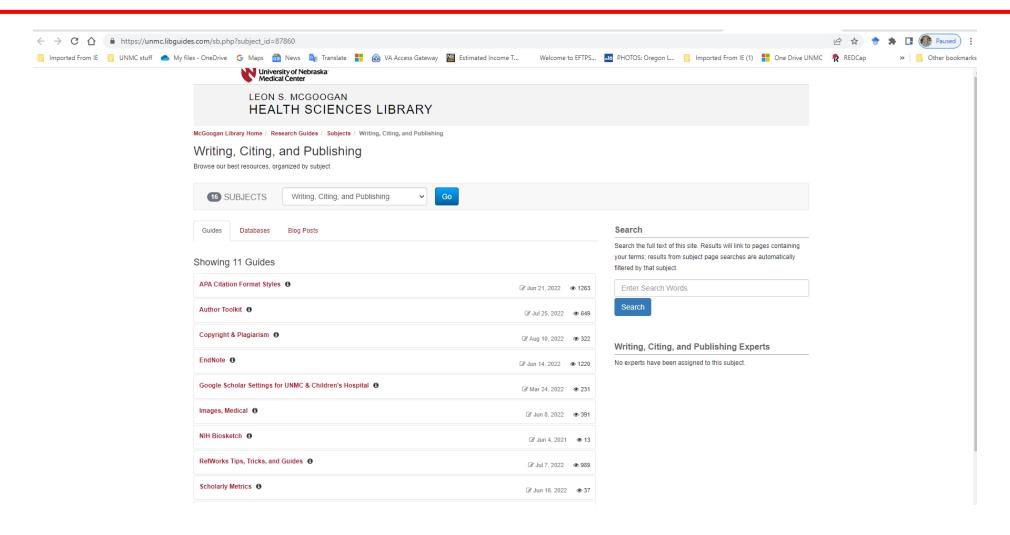


Manuscripts

- Consider target journal first and foremost
 - Discuss with mentor
 - Is this preprint worthy?
- Review author guidelines for that journal
 - They are specific; more journals are "kicking out" submissions after review by publishing staff that overlook these guidelines.
 - Be ready to respond and resubmit (reject and allow resubmission)
 - Be ready for rejection and next submission
 - Try to address criticisms without passion (negativity) and move it to next journal



Useful Guides for Basic Publishing for UNMC https://unmc.libguides.com





Manuscript Writing Workshops

- Child Health Research Institute (CHRI)
 - Writing interest group
- PHAR 814 1 credit manuscript writing class in the Department of Integrative Physiology & Molecular Medicine
- Office of Graduate Studies pending
- Department of Internal Medicine Writing Group



Grant Submissions: A needed skill

- Grant writing workshops
 - CTR 901/903 to refine project
 - Mentor guidance
- IDeA-CTR workshop
- Office of Postdoctoral Education Programming at UNMC Website
- Hannover contract—recorded lectures available (https://www.unmc.edu/com/research/hanover/index.html)
- VCR Research Editorial Office (see website);
 \$32/hour
- NIH with institute specific workshops (NCI, NIDDK)
- CHVR UNMC

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Workshop

Grant Writing is an essential skill for any successful research scientist or academic. The Office of Postdoctoral Education therefore offers frequent grant writing workshops for our scholars.



Grant Writing Seminar with Paul Casella, 8 June 2022

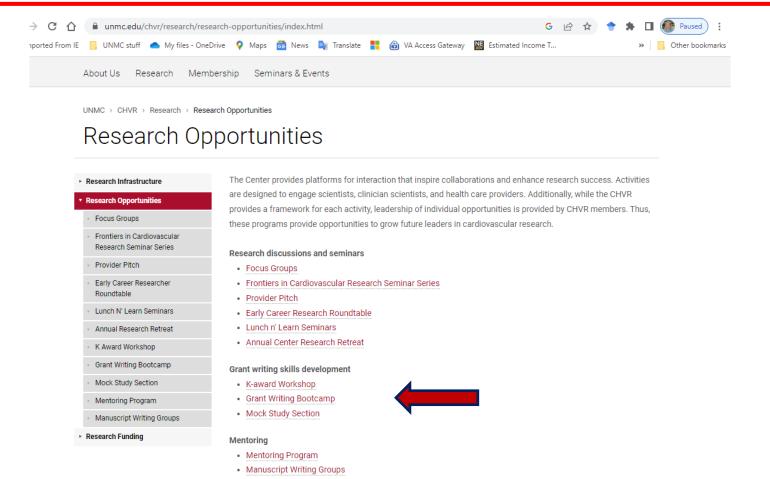
Paul Casella, an adjunct professor and consultant to the faculty at the University of Iowa Carver College of Medicine, presented a workshop on Writing for Publication, Writing Effective NIH Proposals, Strategies for Speaking for Success, and Effective Medical and Scientific Presentations. Presented by the UNMC Office of Postdoctoral Education and Great Plains IDeA, Clinical and Translational Research.

Paul Casella: Writing Effective NIH Grant Applications

Paul Casella: Recent Recordings of Professional Development Seminars, University of Iowa



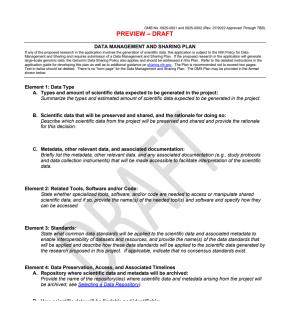
Center for Heart and Vascular Studies UNMC

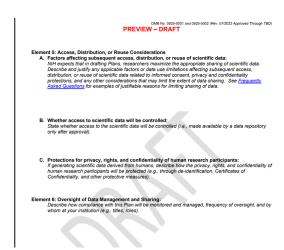




Research Data Management

- This is already mandated at the VA for those applying for VA Research Funding.
- This is a new require for NIH funding as of January 2023.
- Specific requirements for genomic information.
 - https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies







Funding Sources Internal When Starting Out: COM Internal Grants

(https://www.unmc.edu/com/research/internal-opportunities-grants/index.html)

- Program of Excellence Physician-Scientist Training Program (Jr. faculty, retention of fellows)
 - \$200K total over 2 years
 - Developed to provide research-oriented residents/fellows or junior faculty the opportunity to develop careers in biomedical research
- Mary and George White Fund for Medical Research (Jr faculty)
 - \$55K, one award/year
 - Aim: to push the limit of breakthrough thinking and go outside the constraints of "safe science."
- Frances E. Lageschulte and Evelyn B. Weese New Frontiers in Medical Research Fund (All ranks)
 - \$50K per year
 - Aim: projects that explore innovative directions in medical science and offer the greatest hope for significant improvement in healthcare.



More Internal Options: Office of the VCR https://www.unmc.edu/vcr/funding/

- Clinical Translational Research Mentored Scholar Program (CTR-MSP)
 - \$25K / 1 year
 - Reviewed monthly
- Core facility vouchers
- Diversity grant
 - \$50K / year x 2 years
 - Focus is on retaining diverse faculty or those committed to research in this area
- Ittner Pediatric Fund Program and Peds Research Grants
 - \$45K for one year and varies but available quarterly
- Otis Glebe Research Foundation
 - \$90,000 to emphasize translation of lab findings to clinical practice and applying research findings to the community to enhance adoption of best practices.

IDeA CTR

https://gpctr.unmc.edu/2021/09/10/pilot-funding-opportunities/



Pilot grant awards \$50K/year

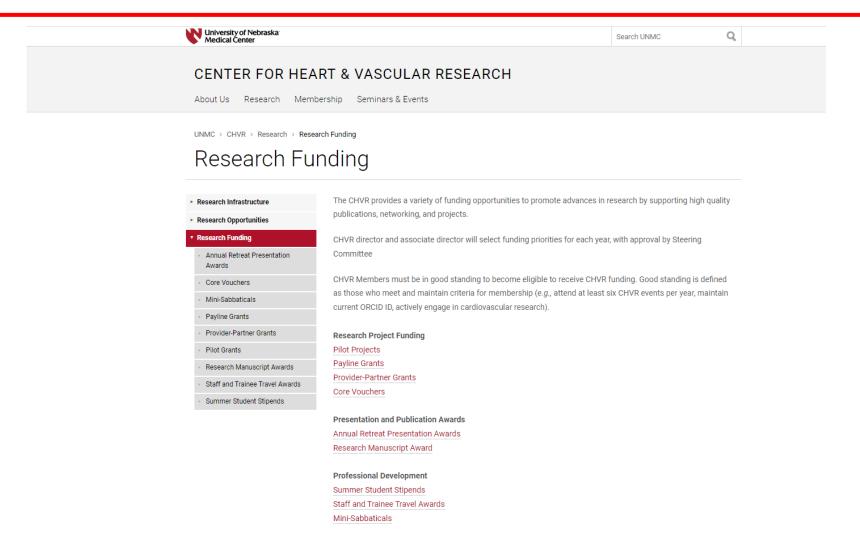
- Team Development
- Team Research
- Heart and Vascular Research
- Tech Transfer (to facilitate translation)

Research Studios

- (1) review of an aims page
- (2) grant review before submission
- (3) brainstorming session for investigators who have hit a funding roadblock



Research Resources: UNMC Center for Heart and Vascular Research (CHVR)





Funding Sources External https://www.unmc.edu/vcr/about/grl.html

- NIH K/R awards
- Society grants programs often have targeted funding for early investigators (e.g. AHA, ASN, ASCO, ACR)
- Foundations relevant to your research (e.g. March of Dimes, Alzheimer's Association, JDRF, Leukemia and Lymphoma Society)
- Know the aims of these organizations, read the RFA carefully to be sure your work fits their scope
- Industry funded studies



Research Resources: Center for Clinical and Translational Research https://www.unmc.edu/cctr/

- Research resources page is most helpful
- https://guides.unmc.edu/books/research-handbook
- Study specific items with links
 - Sponsored Projects Administration (SPA)
 - UNeHEALTH (the contracting and fiscal arm for industry-funded clinical trials on behalf of University of Nebraska Medical Center)
 - UNeMed (the technology transfer & commercialization office for UNMC and UNO)
 - Budget construction (Katie Penas)
 - Clin Trials.gov registration
 - IRB



Sponsored Projects Administration (SPA)

- Known as Grants and Contracts at other academic centers
- Submissions for all grant applications must be sent to them for review and approval on an institutional level
 - Submission approval is through ADIS (Academic Department Information System)
 - Submission is usually done by a grant manager or admin in your division / department
 - They need time, so with major NIH deadline, give them at least a month's heads up, and they will tell you deadlines for your submission and upload (maybe 1-2 weeks, sometimes longer)



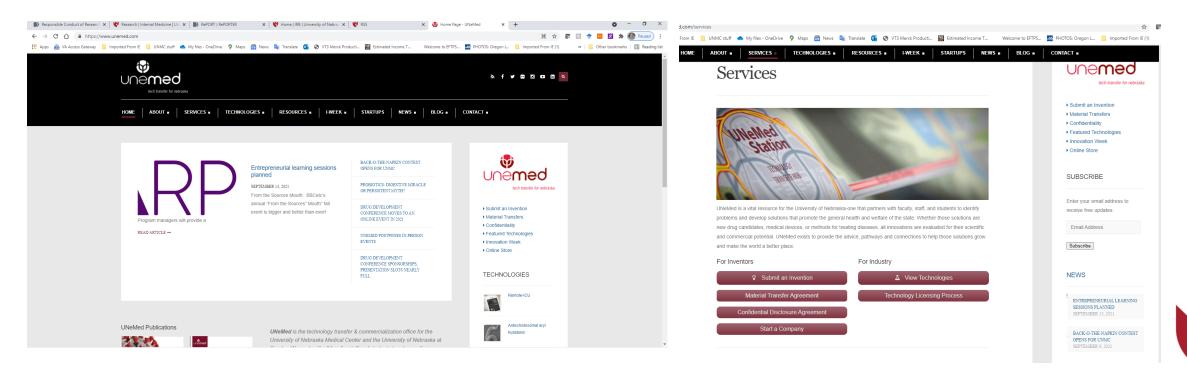
UNeHealth https://www.unmc.edu/spa/clinical-trials/unehealth/index.html

- Serves to facilitate the growth and development of industry-funded clinical research
- Confidentiality Agreements
- Compassionate use agreements and EUA's
- Housed in the CCTR and acts as the contracting arm for industry-funded clinical research on behalf of UNMC.
 - A single "front door" for industry sponsored clinical trial contracting
 - Efficiencies to best support investigators conducting clinical research
 - Clinical research contracting resources for the enterprise



UNeMed https://www.unemed.com/

- Technology transfer (patents, material transfer agreements [MTA], CRADAs)
- Advancing and commercializing biomedical technology



Make sure of the following: if humans or human data are involved.....

- Does your project require IRB approval?
 - Is this a clinical study that involves subject interaction/intervention?
 - Or is it health information access?
 - Is it using a data base that requires institutional approval/CRADA or MTA/project proposal approval?

https://www.unmc.edu/irb/

 Policies and procedures manual, IRB deadlines, access to Research Support System (RSS) application.

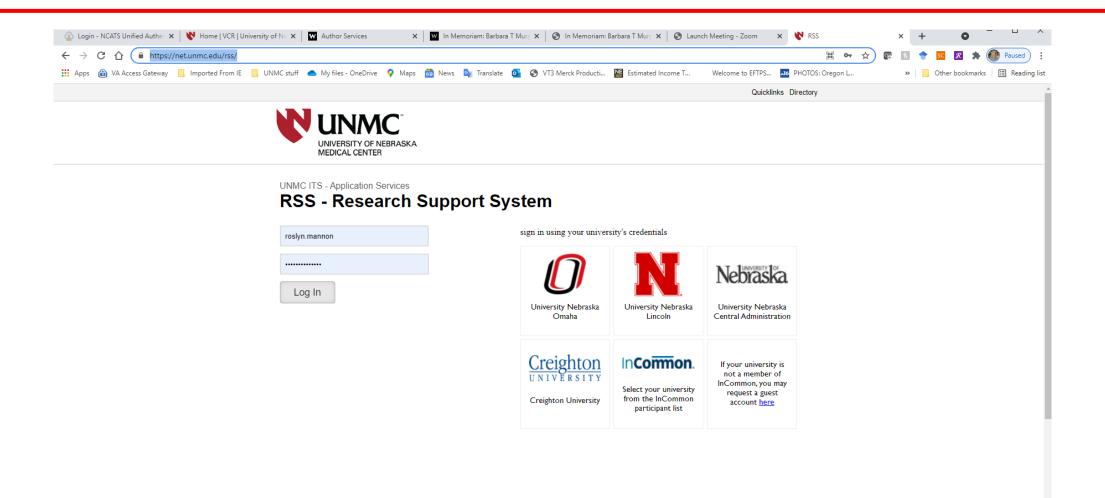


Regulatory Approvals: RSS

- Institutional Animal Care and Use Committee (IACUC)
- Institutional Review Board (IRB)
 - You can reach out in advance to get advice
 - Even if you do not need an IRB, you may need an exemption letter
- If you have not done this before, get help:
 - Ask your mentor
 - Ask a member in your division
 - Ask the coordinators for these committees

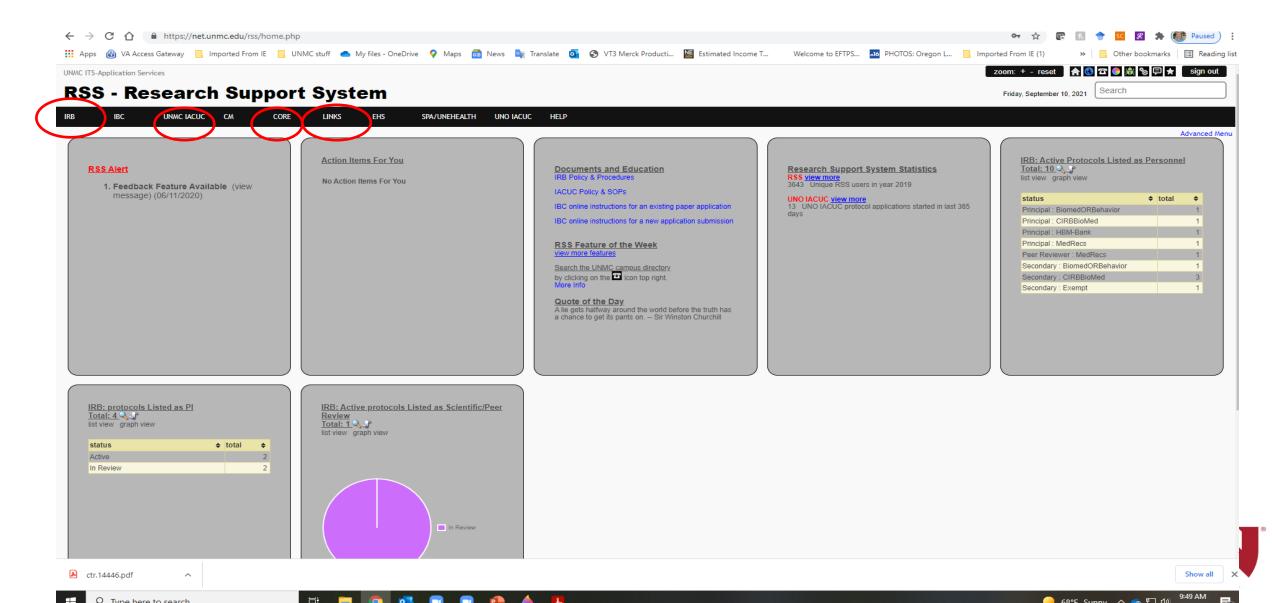


Research Support Services: https://net.unmc.edu/rss/

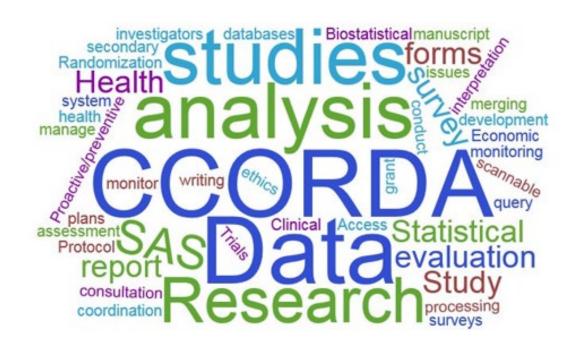




RSS Login



More Research Resources (UNMC Specific)



- Center for Collaboration on Research Design and Analysis (CCORDA) (College of Public Health, Dr. Fang Yu)
- Clinical Data Feasibility using EMR (Purnima Guda, PhD)
 - Crane/i2b2
- Database Tools (Ashok Mudgapalli, PhD)
- Recruitment specialists



UNMC Clinical Research Cores – typical of other medical centers

- Investigational Pharmacy
- Investigational Pathology
- Biobank lab
- Research nursing core
 - Rent a research nurse for clinical projects
- Insurance predeterminations and pre-authorizations



Final words

- Identify a suitable mentor: they may not be in your department.
- Start small and work up.
- It is really your ideas and energy that will keep things going
- Hire great people!
- As PI, you are responsible for all aspects, so make sure you have the skills, training, and mentorship for clinical interventional studies. If not, consider being a coinvestigator first, and "learning the ropes".



