



UNC
CENTER FOR
WOMEN'S HEALTH
RESEARCH



Resource Guide
Catalyzing Research
Information for women's health investigators

Table of Contents

Welcome..... page 3

About the Center..... page 4

Situated in Southern Village..... page 4

Pleasant Working Environment..... page 4

Getting to the Center..... page 5

CWHR Services to Investigators..... page 6

CWHR Administered Study Phases....page 7

Document Review, Creation
& Visualization..... page 8

Example of a Timeline..... page 11

Services to Researchers
by Grant Size..... page 14

Accessing CWHR Services..... page 19

Specific to the Depart. of ObGyn..... page 19

Campus Contacts & Information..... page 20

Course Offering..... page 21

Contact CWHR

Street Address: 104B Market Street
Chapel Hill, NC 27599

Campus Box: 7521

Telephone: (919) 843-7720

Fax: (919) 843-7364

Email: cwhr@unc.edu

Website: www.cwhr.unc.edu

Center Directory

Wendy Brewster, MD, PhD
Director
(919) 843-2933
brewster@med.unc.edu

John M. Thorp, Jr., MD
Deputy Director
(919) 843-7850
thorp@med.unc.edu

Wanda Nicholson, MD, MPH
*Director of Obesity & Diabetes
Research Core*
(919) 843-7116
wanda_nicholson@med.unc.edu

Tracey A. Conrad, CPA
*Assistant Director of Research
Administration*
(919) 843-7116
tracey_conrad@med.unc.edu

Jennifer Edwards
Grant Administrator
(919) 843-3210
jennifer.edwards@unc.edu

Tawanda Harvey
Lead Account Manager
(919) 843-9329
teharvey@email.unc.edu

Jennifer Rumbach
*Public Information Officer/
Office Manager*
(919) 843-7676
jrumbach@email.unc.edu



The entrance to 104B Market Street, home of the Center for Women’s Health Research.

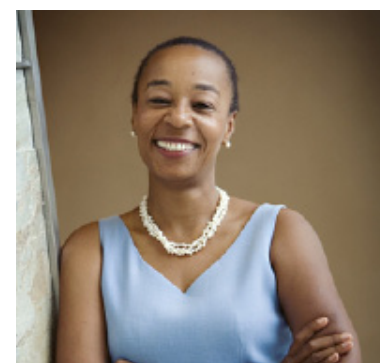
Welcome

The Center for Women’s Health Research (CWHR) at UNC welcomes you to the University of North Carolina.

The mission of the Center for Women’s Health Research at UNC is to improve women’s health through research by focusing on diseases, disorders and conditions that affect women only, women predominately, and/or women differently than men. We engage in multiple activities to carry out this mission including the following:

- Supporting individual investigators in designing studies and writing and submitting proposals
- Administering awarded grants
- Helping investigators find and develop the resources they need to conduct their research
- Conducting research with Center faculty members
- Mentoring junior investigators, graduate and undergraduate students

CWHR provides a focal point for women’s health research efforts on campus, stimulating scientific endeavors within, among, and across all Schools, Colleges, Centers, and Institutes on campus. We strive to build partnerships within the University and the community at large, leading to a better understanding of women’s health and wellness and contributing to improved health for all.



If you have an interest in any area of women’s health, healthcare, and/or wellness, please contact us so we can discuss ways in which we might work together. We are happy to have you with us!

Wendy R. Brewster, MD., PhD

Director, Center for Women’s Health Research

About the Center

The North Carolina Program for Women's Health Research was founded in 2000 under the auspices of the UNC Department of Obstetrics & Gynecology.

The previous director, Dr. Katherine Hartmann, and a small staff established the program in its former location at the Cecil G. Sheps Center for Health Services Research.

As the Center grew in size, a decision was reached to officially change CWHR from a departmental program to a center within the UNC School of Medicine. The name was changed in 2004 to "The Center for Women's Health Research at UNC" (CWHR).

In November, 2008, Dr. Wendy Brewster began as the new director and in February, 2009, CWHR moved to its present offices in Southern Village. A new vision and mission was crafted, focusing on increasing research collaborations, identifying new outreach opportunities, and training and supporting the next generation of women's health researchers.



Southern Village boasts is a wonderful community to work and live in.

Situated in Southern Village

Southern Village is a mixed-use Chapel Hill community of shops, restaurants, houses, apartments, townhouses, businesses and offices. CWHR is conveniently located on Market Street, near the village square. There are many events held throughout the year, including a farmer's market each Thursday from March to November and outdoor movies and concerts in the summer.

Pleasant Working Environment

CWHR occupies the "B" side of the building at 104 Market Street and contains a lobby area, offices, rest rooms, a kitchen, individual computer carrels, and outside porch and patio seating areas.

The Center conference room seats up to 15 and contains a large pull-down screen, LCD projector/laptop, white boards and flip charts. Most internal CWHR meetings and events are held in the conference room. It is also available for use by other colleagues in women's health research for educational and professional meetings. The kitchen is fully-equipped with a refrigerator, stove, microwave, dishwasher, and coffee-maker. Staff may use the kitchen area for food storage and cooking. Each person is responsible for clean-up after using the kitchen and common areas.

CWHR provides several computer-equipped, internet accessible office carrels for use by research collaborators, faculty, interns, graduate research assistants, work study students, and others during regular office hours. Prior arrangement is helpful but not required. In addition, the building is Wi-Fi enabled through the School of Medicine.

Getting to the Center

The Center is located off-campus in Southern Village at **104B Market Street, Chapel Hill.**

From points West: From Interstate 40 East, take Carrboro exit (Hwy 54). Continue for several miles on Hwy 54 through Carrboro in right lane. Exit RIGHT at 15-501 South/Pittsboro exit. Travel approximately 1.5 miles to intersection with Market Street at Southern Village. Turn RIGHT onto Market Street; turn RIGHT again at first stop sign and immediate RIGHT into parking lot; enter through Main Entrance.

From Raleigh and points East: From Interstate 40 West, take exit 273A (Hwy. 54 West/Chapel Hill/Raleigh Road). Continue STRAIGHT staying in right lane. Take 15-501 South exit at overpass (just past Glen Lennox shopping center on right). Continue STRAIGHT in right lane. Take 15-501 South exit (Chapel Hill/Pittsboro); turn LEFT onto 15-501 South toward Pittsboro. Travel approximately 1.5 miles to intersection with Market Street at Southern Village. Turn RIGHT onto Market Street; turn RIGHT again at first stop sign and immediate RIGHT into parking lot; enter through Main Entrance.

From Durham: Take Bypass 15-501 toward Chapel. Continue STRAIGHT staying in right lane for several miles. Take 15-501 South exit (Chapel Hill/Pittsboro); turn LEFT onto 15-501 South toward Pittsboro. Travel approximately 1.5 miles to intersection with Market Street at Southern Village. Turn RIGHT onto Market Street; turn RIGHT again at first stop sign and immediate RIGHT into parking lot; enter through Main Entrance.



Parking/Bus: Parking is free and available in the lot adjacent to the building. Fare-free bus transportation is provided by the Chapel Hill Transit Authority within the Chapel Hill-UNC service area. Transportation to and from campus and other area cities is provided by several transportation services with varying fares. Bus schedules and other information can be obtained at the UNC Public Safety Office or downloaded at their website: <http://www.dps.unc.edu>.

Travel to/from Campus: It is often necessary for CWHR personnel to travel to the main campus for meetings or events. CWHR has a service parking permit available for parking on campus in designated areas (2-hour limit). Bus service from Southern Village to the main campus is also available.

Hours of Operation

Monday - Friday 8:30 a.m. - 5:00 p.m.

The Center operates on the University of North Carolina calendar for all holiday observances and other closings (weather, disaster, etc.).



The Center is designed to support the computer needs of investigators and research teams across UNC.

CWHR Services to Investigators

The Center fulfills part of its mission by providing services to women's health researchers through all phases of project development, **regardless of their home department**. Services include:

- Facilitating new areas of research
- Helping investigators build research teams
- Assisting with pilot design and methodology
- Creating timelines and giving project management guidance
- Supporting all aspects of proposal writing and submission
- Designing and building databases
- Assisting with pre-award budgets
- Supporting progress reporting and submission
- Providing oversight and guidance for research team start-up
- Being the post-award grant administrator
- Monitoring, coaching and feedback, particularly for new investigators

We have defined our services and the process for accessing them in collaboration with the Department of Obstetrics and Gynecology. In general, the same guidelines will apply to investigators from departments outside ObGyn and from other schools, centers and institutes. If you are outside the School of Medicine and/or are not part of the Department of ObGyn and would like to work with the Center on a grant proposal/submission, please contact Jennifer Rumbach at jrumbach@email.unc.edu to discuss ways in which the Center can work with you and your department/division.

In the following pages you'll find the phases of a CWHR administered study, an example of our timelines for submissions, and a list of the writing, editing and visualization services we offer. How CWHR categorizes the services we can offer, based on the size of a study, is explained in depth beginning on page 10.

Phases of a CWHR Administered Study

Services are dependent on availability of personnel and on the type of proposal.

Phase 1: Preliminary Planning

- Structure and conduct literature reviews
- Build research team
- Assist with pilot design and methodology
- Create timelines and provide project management
- Help develop research questions
- Monitor and provide feedback

Phase 2: Pilot Study

- Help identify potential funding sources
- Strategize and guide decision process
- Support all aspects of proposal writing and submission
- Assist with pre-award budgets
- Create timelines and provide project management
- Monitor and provide feedback
- Devise tools and databases
- Post-award administration

Phase 3: Main Study

- Assist with study design and methodology
- Help identify potential funding sources
- Strategize and guide decision process
- Support all aspects of proposal writing and submission
- Assist with pre-award budgets
- Create timelines and provide project management
- Monitor and provide feedback
- Post-award administration

Phase 4: Data Analysis & Reporting

- Oversight for research team start-up
- Implement timelines, schedules, project management
- Devise tools and databases
- Support progress reporting and submission
- Support IRB submissions
- Provide coaching on data analysis and conclusions
- Assist with posters and presentations
- Provide support for manuscript writing teams
- Post-award administration

Document Review, Creation and Visualization

The Center supports document review, creation and visualization both in-house and through our cadre of independent contractors.

| Level | Name | Activities |
|---------|--|---|
| Level 1 | Formatting | <p>Level 1A ensures consistency in the layout of the pages of the document, specifically section titles, headers, footers, Tables of Contents, page numbers, etc.; requires cursory knowledge of general format for a particular RFA/RFP</p> <p>Level 1B ensures alignment of the document with a template, or with company, journal, or regulatory guidelines (eg, RFA for a grant proposal or RFP for a contract proposal); requires a detailed understanding of all elements of the RFA/RFP/guidelines under which the document is produced</p> |
| Level 2 | Proofreading <i>(often termed copy editing)</i> | <p>Level 2A looks at internal consistency within a single document; reviews text, numbers, and language, does random reference validation checks, and reviews style and mechanics, specifically spelling, grammar, punctuation, use of capital letters, word use, use of units of measure, and abbreviations; may review tables and figures and make suggestions for changes, but is not involved in content; requires knowledge of appropriate usage of grammar and punctuation and ability to use AMA Style Manual and a current Medical Dictionary as references</p> <p>Level 2B compares two versions of the same document or similar content from two related documents (eg, protocol and proposal) and reviews for consistency, duplication, random reference validation checks, and style and mechanics as in Level IIA; requirements same as above plus ability to read and integrate information</p> |
| Level 3 | Microediting <i>(approaches what is often called content editing)</i> | Review text at or below paragraph level to improve grammar, word choice, flow, voice, style, logical inconsistencies, clarity, and to reduce duplication (eg, table versus text); may review existing tables and figures, and edit to create a “common look and feel” and make changes related to clarity or presentation; requires strong copyediting skills, basic knowledge of the subject matter or therapeutic area, and the ability to comprehend and communicate scientific concepts |
| Level 4 | Macroediting <i>(often called content editing)</i> | Evaluate content and organization to ensure congruency, tone, structure, consistency, logic, and completeness; review from a reader’s perspective to ensure that document meets needs of the audience; manages and/or provides input on the concept, study design, and other elements; generally focused at the paragraph level and higher; requires detailed understanding of the RFA/RFP/guidelines under which the document is written, and a strong knowledge of the subject matter or therapeutic area (others who are stronger in the subject matter or therapeutic area should be asked to review the document from their perspectives); must be able to interpret and communicate data and information from clinical and nonclinical areas |

| Level | Name | Activities |
|---------|------------------|--|
| Level 5 | Co-authorship | This level includes writing or rewriting select sections as agreed upon with the prime author(s) and is done in conjunction with macro- and micro-editing. Involves gathering, reviewing, and analyzing information and data pertinent to the assigned sections, and ensuring that the resulting document contains and communicates the information necessary to meet internal and external customer needs. Requires same abilities as stated for macro- and micro-editing, in addition to ability to generate verbiage de novo. Requires in-depth knowledge of the subject matter, therapeutic area, or type of proposal. It also requires the author to work closely with the prime author to understand what he/she wants or expects; joint agreement on who writes what content is required. The writing process is an iterative one in which the co-author drafts appropriate sections and submits to the prime author for review. If the co-author also serves as the grant coordinator (as for more complex proposals), requires a detailed understanding of the RFA/RFP or other guidelines specific to the proposal. |
| Level 6 | Prime authorship | This is the most complex level in which the author works with PI(s) or Director(s) to conceptualize, generate, write, and coordinate development of an entire proposal (eg, grant or contract proposal such as the MFMU, TECT, WRHR, CCHN, RMN, CCTN, and others) or document (eg, a Manual of Procedures, ten-year plan, or business case). The PI or Director may write certain sections (eg, a concept proposal) to be included, but the author typically writes the first draft, gets input, revises, and finalizes the document to the satisfaction of the PI (and/or Director). (NOTE: This does not include work with manuscripts; there are ethical guidelines that apply to the writing and editing of manuscripts that do not apply to grants and other work documents.) This level involves gathering, reviewing, and analyzing pertinent information and data, planning the document architecture and content, writing all or most sections of the proposal, incorporating work of any other writers, and ensuring that the document contains and communicates the information necessary to meet internal and external customer needs. It is necessary for the author to develop and gain agreement to a timeline for the production of the document, engage other disciplines, organizations, and individuals as needed, and ensure the timely delivery of information from said individuals or groups. Primary authorship requires a detailed understanding of the RFA/RFP/ or other guidelines specific to the proposal, and in-depth knowledge of the subject matter, therapeutic area, or proposal type. It also requires the author to work closely with the PI or Director to understand what he/she wants or expects; joint conceptualization and agreement on content is required. The writing process is an iterative one in which the primary author conceptualizes, tests assumptions, drafts, reviews with whoever commissioned the document, and finalizes the document on behalf of the PI or Director. |

| Level | Name | Activities |
|------------------|------|---|
| Special Services | | <p>SS1) Creation of tables and/or original diagrams and figures, which often requires joint conceptualization with the author or authors; requires indepth knowledge of PowerPoint or Visio and ability to work collaboratively with author(s) to conceptualize scientific principles, study design, and other elements requiring illustration</p> <p>SS2) Provide appropriate samples of materials from pervious submissions, such as various types of letters (support, commitment, budget agreement), and Facilities and Environment sections; requires knowledge of repository where these examples reside, and ability to select appropriate documents</p> <p>SS3) Generate drafts of materials for prime author's consideration; may be various letters or facilities and environment sections; updates and/or rewords existing materials to fit the new situation; requires knowledge of the repository where these materials reside, ability to select appropriate documents, knowledge of where to go for updated information, and ability to rewrite and refocus as dictated by the situation.</p> |

Review of a document assumes that someone else is the prime author of a document (eg, a grant or contract proposal) that an editor can review and edit at multiple levels. Creation of a document assumes that the individual actually writes all or part of the document. The following table provides a brief description of the levels of work involved in six levels of document review. A higher Level number means an increasing level of complexity that requires more in-depth knowledge to successfully execute.

Contact Jennifer Rumbach at jrumbach@email.unc.edu with your list of requested services and she will help match you with the appropriate individual.

Example of a Timeline

For ALL proposals for which the Center will be the submitting and administrating agency, regardless of where it is going, please notify Jennifer Rumbach at jrumbach@email.unc.edu as soon as you begin planning a submission. Send her the proposed submission date, the agency, and a link to the funding opportunity announcement. We prefer this information at least three months in advance of the submission due date. CWHR will generate a timeline and discuss it with you; at the same time we will agree on what Center services you will be using. CWHR personnel will recap the conversation and revise the timeline per the conversation, send to you, and put the dates in the CWHR work queue.

Exception to the three month notification: We recognize that some announcements are released with less than a three month window for response; if you have less than three months to respond, we will follow the same process as outlined above. Following the discussion on the timeline and critical dates, if you commit to meeting the deadlines discussed, we will be happy to work with you. As you are working on your proposal, if you decide to change your submission date, please notify CWHR.

A week-by-week breakdown follows. Please keep in mind this timeline is generated uniquely for each project and may change depending on the scope of your project and required resources.

Timeline Week-by-Week

Week 1:

- Conversations with study team collaborators

Week 2:

- Finalize study design
- Identify reviewers and request participation
- PI registers at Grants.gov if necessary

Week 3:

- Initial draft of specific aims
- Determine who will provide letters of support and request

Week 4:

- Work on Research Plan
- Draft of Specific Aims to reviewers
- Draft 1 of Human Subjects complete
- Budget Draft 1 developed
- CWHR notified if there will be sub-contractors
- Identify all players
- Draft Letters of Support

Timeline Week-by-Week continued...

Week 5:

- Comments on Specific Aims returned and incorporated
- Human Subjects: Draft to reviewers
- Initials meeting with Tracey regarding subcontracts
- Make a list of Biosketches needed
- Finalize and send letters of support
- Initial draft of resources section

Week 6:

- Continue work on Research Plan
- Draft 1 of Research Plan submitted to reviewers
- Human Subjects: Comments from reviewers incorporated
- Budget Draft 1 reviewed, changes returned
- CWHR contacts subcontractors
- All players contacted for Biosketches
- Define Appendices

Week 7:

- Research Plan comments returned
- Human Subjects: Draft 2 sent to reviewers
- Budget justification draft 1
- Subcontracts work through their process
- Resources: review and change as needed

Week 8:

- Continue to work on Research Plan
- Send Research Plan to reviewers for final review and comments
- Human Subjects: Incorporate final comments
- Budget draft 2: Changes for justification returned
- Subcontracts continue to work through their process
- Appendices mock-up

Week 9:

- Research Plan comments returned and incorporated
- Subcontracts continue to work through their process
- Biosketches turned in to CWHR
- Any outstanding letters of support turned in to CWHR
- Ensure resources reflect design needs
- All Appendices complete

Week 10:

- Research Plan finalized
- Final changes to budget and justification due
- Subcontracts returned to CWHR
- Letters of support finalized
- Resources finalized
- Appendices finalized

Timeline Week-by-Week continued...

Week 11:

- CWHR inputs Research Plan
- Budget and justification submitted in Ramses
- Final upload and review by PI
- All electronic approvals completed

Week 12:

- Final review, integrate and upload to OSR for approval

Week 13:

- Actual submission and confirmation

Timeline for NIH R03 Grant Proposal Electronic Submission February 16, 2012

| | Nov. 16-22 | Nov. 23-30 | Dec. 1-7 | Dec. 10-14 | Dec. 17-21 | Dec. 24-31 | Jan. 01-Jan. 4 | Jan. 7-11 | Jan. 14-18 | Jan. 21-25 | Jan. 28 - Feb. 1 | Feb. 4-8 | Feb. 11-15 |
|---|--|--|--------------------------------|-------------------------------------|---|---|---|--|---|---|--|--|-----------------------------------|
| Research Plan | Conversations with study team, collaborators | Finalize study design | Initial Draft of Specific Aims | Work on Research Plan | Comments on Specific Aims returned and incorporated | Continue work on Research Plan | Comments returned and incorporated | Continue work on Research Plan | Comments returned and incorporated | Research Plan finalized by Jan 1 (Fri) | To CWHR for putting into Cayuse (early in week is best) | | |
| Reviewers | | Identify reviewers and request participation | | Draft of Specific Aims to reviewers | | Draft 1 of Research Plan to reviewers | | Send to reviewers for final review and comments | | | | | |
| Human Subjects | | | | Draft 1 of Human Subjects | Draft 1 to reviewers | Comments incorporated | Draft 2 to reviewers | Comments incorporated | | | | | |
| Budget | | | | Budget Draft 1 | | Budget draft 1 reviewed, changes returned | Justification draft 1 | Budget draft 2; changes for justification returned | | Final changes to budget and justification | Budget & justification Ramses submission Mon, Jan. 23 | | |
| Subcontract | | | | Notify CWHR if sub-contractors | Initial meeting with Tracey re: subs | CWHR contacts sub(s) | Subcontracts work through their process | Subcontracts work through their process | Subcontracts work through their process | Subcontracts returned by Tues., Jan. 22 | | | |
| Biosketches | | | | Identify All Players | Libt. Biosketches needed | Contact people for Bios | | | Biosketches returned by Fri, Jan. 18 | | | | |
| Letters of Support | | | Determine who and request LOB | Draft Letters of Support | Finalize and send LOB | | | | LOB - FIU any outstanding ones | LOB returned by Fri, Jan. 25 | | | |
| Resources | | | | | Initial draft of Resources section | | Review and change | | Ensure resources reflect design needs | Resources complete by Fri, Jan. 25 | | | |
| Appendices | | | | | | Define Appendices | | Appendices Mock Up | All materials compiled | PDF files by Fri, Jan. 25 | | | |
| Upload to Cayuse and approvals by PI | | | | | | | | | | | Upload into Cayuse available to PI for review and change | Final review, integrate and upload to OSR by Mon, Feb. 4 | Receive confirmation Fri, Feb. 10 |
| eFPI/Grants.gov | | FI registered at Grants.gov?? | | | | | | | | | Electronic approvals complete | | Actual submission Thurs., Feb. 14 |
| Proposal Due | | | | | | | | | | | | | NIH Due date 5 pm Feb. 16, 2012 |
| Holidays | Holiday- Nov 22, 23 | | | | | Holiday- Dec. 24, 25, 26 | Holiday- Dec. 31, Jan 1 | | | Holiday- Jan 21 | | | |
| Vacations | | | | | | | | | | | | | |
| Other times | | | | | | | | | | | | | |

NOTE: In addition to the above, other documents required for submission include an abstract, a narrative, statements of inclusion, an enrollment table, possibly others. Please review your RFA.

Example of a CWHR submission timeline generated for each proposal submission that goes through the Center. Timelines may vary based on the nature of the submission

Services to Researchers by Grant Size

We have divided proposals into categories which we have deemed orange, yellow, green and red. Definitions of each category, the assistance CWHR can offer for each category, specific details of how to access our services and our submission process are in the pages that follow.

Center personnel do not work with proposals with no indirect funds associated with them unless a mechanism to cover the cost of our involvement is negotiated in advance with your division director, department chair or school dean. If we work with you on a proposal and the proposal is submitted through the Center, we expect to be the grant administrator.

Through our Clinical Trials Unit, we provide extensive support to investigators involved with the conduct of industry sponsored and initiated clinical trials. Specific details of the assistance provided and how to access these services follow.

Sweat equity/in-kind projects; all intramural projects plus extramural projects below \$100,000 are considered Orange

Extramural projects that are non-federal/state funded with values from \$100,000 to \$250,000 are considered Yellow

Extramural projects—all federal/state funded plus non-federal projects above \$250,000 are considered Green

All Industry sponsored and initiated clinical trials, ranging from \$25-30K to millions are considered Red

Orange Projects

Sweat equity/in-kind projects; all intramural projects plus extramural projects below \$100,000 are considered Orange

Funding Sources

- University
- Foundations
- Professional organizations
- State and local governments

Principal Investigator Time

- Minimal

Salary Expectations

- No Salary Support

Indirects

- None

Assistance CWHR Can Offer

Center assistance for orange projects is funded at the discretion of the Division Director/ Department Chair, or Dean. If you need assistance with a project from this level, please discuss with your Division Director or equivalent before contacting the Center.

- Database, data management and analysis
- Guidance on specimen collection, storage, analysis
- IRB submissions
- Mentorship
- Access to work study students, fellows, medical students, interns, etc.
- Application preparation and submission
- Grant administration
- Progress reports
- Project management support for recruitment and implementation
- May be able to broker PRN, RA or research nurse time

Yellow Projects

Extramural projects that are non-federal/state funded with values from \$100,000 to \$250,000 are considered Yellow

Funding Sources

- University
- Foundations
- Professional organizations
- State and local governments
- Federal

Principal Investigator Time

- Dependant on salary support

Salary Expectations

- Minimal salary support

Indirects

- Depends on funding source; typically foundation rates are lower than federal rates

Assistance CWHR Can Offer

Center assistance for some projects at this level may require funding support from your Division or Department. Please discuss with your Division Director or Equivalent before contacting the Center.

- Database, data management and analysis
- Guidance on specimen collection, storage, analysis
- IRB submissions
- Mentorship
- Access to work study students, fellows, medical students, interns, etc.
- Application preparation and submission
- Grant administration
- Progress reports
- Project management support for recruitment and implementation
- May be able to broker PRN, RA or research nurse time

Green Projects

Extramural projects—all federal/state funded plus non-federal projects above \$250,000 are considered Green

Funding Sources

- Foundations (few)
- Federal

Principal Investigator Time

- Usually greater than salary support

Salary Expectations

- Minimum 15% salary support expected by funding agency

Indirects

- Depends on funding source; typically foundation rates are lower than federal rate

Assistance CWHR Can Offer

Center assistance for projects at the green level is supported by the Department of ObGyn through a yearly contribution to the Center. If you are outside the Department of ObGyn please contact the Center to determine how we will work together.

- Database, data management and analysis
- Guidance on specimen collection, storage, analysis
- IRB submission
- Mentorship
- Access to work study students, fellows, medical students, interns, etc.
- Application preparation and submission
- Grant administration and progress reports
- Project management for recruitment and implementation
- Dedicated study staff - RA, research nurse, study coordinator; CWHR can assist with job descriptions, posting, screening, interviewing, all aspects of hiring process
- Manuscript, abstract, poster preparation

Red Projects

All Industry sponsored and initiated clinical trials, ranging from \$25-30K to millions are considered Red

Funding Sources

- Commercial - pharmaceutical companies and CRO's

Principal Investigator Time

- Dependant on complexity of the study and support staff

Salary Expectations

- Salary support highly variable; physician time may be minimally covered but much is in-kind

Indirects

- Minimum of 28% (non-negotiable)

Assistance CWHR Can Offer

Assistance for clinical trials is available through the CWHR Clinical Trials Unit (CTU). Industry sponsored and initiated clinical trials have a unique process to follow. Please see the CWHR Clinical Trials Unit Process Manual for details. Please discuss with your Division Director or Equivalent, then contact Jennifer Rumbach at jrumbach@email.unc.edu for details.

- Navigating the Office of Clinical Trials approval process
- IRB submissions
- Evaluating protocols and recruitment potential
- Establishing cost of protocol
- Budget negotiations
- Sponsor and study vetting
- Recruitment and enrollment tracking
- Monitoring financial health of trials

Narrative for Accessing CWHR Services Specific to the Department of ObGyn

The Department of ObGyn, through its Research SWOT Committee, has decided that funds the department provides to the Center for research support are best used for developing and submitting GREEN and RED proposals. YELLOW proposals (see definitions below) may be supported, but a discussion between Center and Division/Department personnel is needed to determine whether Center assistance is covered by Departmental funding, or whether the Division would need to provide funding for the support. YELLOW proposals deemed to be outside the Departmental funding stream and all ORANGE proposals will need to be submitted and administered by the PI or someone in their division/department unless there is prior agreement on funding the Center for this work. CWHR is willing to assist in helping individuals within ObGyn learn how to do this; please contact Jennifer Rumbach at jrumbach@email.unc.edu for assistance.

For ALL proposals for which the Center will be the submitting and administrating agency, regardless of where it is going, please notify Jennifer Rumbach at jrumbach@email.unc.edu as soon as you begin planning a submission. Send her the proposed submission date, the agency, and a link to the funding opportunity announcement. We prefer this information at least three months in advance of the submission due date. CWHR will generate a timeline (see example, page 12) and discuss it with you; at the same time we will agree on what Center services you will be using. CWHR personnel will recap the conversation and revise the timeline per the conversation, send to you, and put the dates in the CWHR work queue.

Exception to the three month notification: We recognize that some announcements are released with less than a three month window for response; if you have less than three months to respond, we will follow the same process as outlined above. Following the discussion on the timeline and critical dates, if you commit to meeting the deadlines discussed, we will be happy to work with you. As you are working on your proposal, if you decide to change your submission date, please notify CWHR.

Orange Projects

Center assistance is funded at the discretion of the Division Director

Yellow Projects

Center assistance may require funding from your Division

Green Projects

Center assistance is supported by ObGyn

Red Projects

Assistance for clinical trials is available through the CWHR Clinical Trials Unit(CTU)

Campus Contacts & Information

MyUNC.edu

- Access campus directory of faculty, staff and students
- Employee services and resources
- UNC calendars, events and announcements

Center for Women's Health Research - Dept. #4202

Phone: (919) 843-7720 Fax: (919) 843-7364

General Information

| | |
|--------------------------------------|----------|
| Health Sciences Library | 962-0800 |
| Finance Division | 962-2256 |
| Disbursements | 962-0213 |
| Payroll | 962-0046 |
| Purchasing | 962-2251 |
| Human Resources | 843-3599 |
| Mail Services | 962-0473 |
| Public Safety (Parking) | 962-3951 |
| University Advancement (Development) | 962-0329 |
| Work-Study Employment Program | 962-4170 |

www.hsl.unc.edu
finance.unc.edu

hr.unc.edu
fac.unc.edu
www.dps.unc.edu
giving.unc.edu/
studentaid.unc.edu

School of Medicine

| | |
|--|----------|
| Administration (Dean's Office) | 966-4161 |
| Continuing Medical Education (CME) | 962-2118 |
| Information Systems, Office of (OIS) | 966-1325 |
| Lineberger Comprehensive Cancer Center (Admin) | 966-3036 |
| Medical Sciences Teaching Lab (MSTL) | 966-1134 |
| Medical Foundation of North Carolina, Inc. | 966-1201 |
| Sponsored Programs Office | 962-3950 |
| Obstetrics & Gynecology: | |
| Administration | 966-5281 |
| Advanced Laparoscopy & Pelvic Pain | 966-7764 |
| Gynecologic Oncology | 966-1194 |
| Maternal-Fetal Medicine | 966-1601 |
| Midwifery | 843-2490 |
| Reproductive Endocrinology & Fertility | 966-5283 |
| Urogynecology & Reconstructive Pelvic Surgery | 966-4717 |
| Women's Primary Health | 843-7850 |

www.med.unc.edu
www.med.unc.edu/cme
www.med.unc.edu/ois
www.unclineberger.org
www.med.unc.edu/mstl
www.med.unc.edu/medfoundation
www.med.unc.edu/spo

www.med.unc.edu/obgyn

Other Schools

| | |
|--|----------|
| School of Dentistry - Administration | 966-1161 |
| School of Nursing - Administration | 966-3731 |
| School of Pharmacy - Administration | 966-1122 |
| School of Public Health - Administration | 966-3215 |
| Center for Health Promotion/Disease Prevention | 966-6080 |
| School of Social Work - Administration | 962-1225 |

www.dent.unc.edu
nursing.unc.edu
pharmacy.unc.edu
www.sph.unc.edu
www.hpdp.unc.edu
ssw.unc.edu

UNC Research Affiliations & Resources

| | | |
|--|----------|--|
| Carolina Population Center | 966-2157 | www.cpc.unc.edu |
| Cecil G. Sheps Center for Health Services Research | 966-5011 | www.shepscenter.unc.edu |
| Grant Resource Library (<i>searchable databases</i>) | | research.unc.edu/grantsource/ |
| Health Sciences Library | 962-0800 | www.hsl.unc.edu |
| NC TraCS Institute | 966-6022 | tracs.unc.edu |
| Office of Sponsored Research | 966-3411 | research.unc.edu/osr |
| Research at Carolina | | research.unc.edu |
| Research & Economic Development - Vice Chancellor | 962-1319 | research.unc.edu |
| Sponsored Programs Office—School of Medicine | 962-3950 | www.med.unc.edu/spo |

UNC Research Core Facilities

For a searchable database of contacts and information visit the Research Core Facilities and Services website *Search by category (i.e., animal studies, genetics, etc.) or by school (i.e., Arts & Sciences, Medicine, etc.).*
<http://www.med.unc.edu/ott/core-facilities>

UNC Research Protocol Offices

| | | |
|---|----------|---|
| Conflict of Interest Policy Information | 843-5328 | https://cfx3.research.unc.edu/coi |
| Division of Animal Laboratory Medicine | 966-3111 | http://research.unc.edu/dlam |
| Institutional Animal Care & Use Committee (IACUC) | 966-5569 | http://research.unc.edu/iacuc |
| Institutional Review Board (IRB) | 966-3113 | http://ohre.unc.edu |

Other Resources

| | |
|--|---|
| Centers for Disease Control & Prevention | http://www.cdc.gov/about/business/funding.htm |
| Community of Science (<i>worldwide research database</i>) | http://www.cos.com |
| Grants.gov (<i>search all federal funding and information</i>) | http://www.grants.gov |
| HSRProj (<i>searchable database for health services research and public health projects</i>) | http://cf.nlm.nih.gov/hsr_project/home_proj.cfm |
| National Institutes of Health | http://grants1.nih.gov/grants/oer.htm |
| National Science Foundation | http://www.nsf.gov/funding |
| U.S. Department of Agriculture (<i>choose "Researchers" from browse by audience menu</i>) | http://www.usda.gov |
| U.S. Department of Health & Human Services | http://www.dhhs.gov/grants/index.shtml |

Course Offering

Research Administration for Scientists (COMP 918) - Offered Spring semester only

The course covers a range of topics important to any doctoral student in the sciences. Students will learn the basics of writing grant applications and preparing budgets, how the proposal review process works at different agencies, and important aspects of managing research after the proposal is funded e.g., supervising people as well as managing money, scheduling work, and documenting performance while complying with funding agency rules. Additional topics include: setting up a lab; research ethics; misconduct in science; human subject testing; laboratory safety; intellectual property including copyrights, patents, trade marks and trade secrets; technology transfer including licensing, material transfers, and start-up companies; conflict of interest; and the challenges/rewards of bridging the academic/industry divide.

Contact: Timothy L. Quigg, MPA - Associate Chair for Administration & Finance, Dept. of Computer Science

Tel: (919) 962-1777

Email: quigg@cs.unc.edu

Website: www.cs.unc.edu/~quigg/comp918.html

...advancing women's health through research

cwhr.unc.edu



UNC
CENTER FOR
WOMEN'S HEALTH
RESEARCH