

CWHR Ten-Year Plan:

*A Vision for Women's Health
Research at UNC*

2011-2020



UNC
CENTER FOR
WOMEN'S HEALTH RESEARCH

...advancing women's health through research

Table of Contents

2	Message from the Director
3	Mission, Historical Overview and Future Direction
5	Vision, Goals and Objectives
	GOAL 1 Maximize the impact of UNC’s women’s health research by creating strategic alliances and partnerships.
	GOAL 2 Enhance existing research efforts in all areas of women’s health by integrating the NIH Office of Research on Women’s Health goals for the decade into the research agenda at UNC.
	GOAL 3 Strengthen the measurement of long term improvement by re-vamping the NC Women’s Health Report Card to monitor trends in the health of North Carolina’s women over time.
	GOAL 4 Ensure financial stability for the Center beyond 2013.
	GOAL 5 Support existing efforts to advance the careers of women in biomedical fields at UNC.
	GOAL 6 Increase understanding and appreciation of all aspects of women’s health and wellness research through the use of new communication and social networking technologies.
10	Resources
11	Summary
12	Appendices

I. Message from the Director

The Center for Women's Health Research (CWHR) at UNC was established in March of 2000 to support research into diseases, disorders and conditions that affect women only, women predominately, and/or women differently than men. In our first decade, we demonstrated our ability to build collaborations and partnerships across the campus and state, gained clarity about how we would carry out our mission, established a core infrastructure to deliver key services to women's health investigators, and defined processes for our ongoing operations. We were instrumental in the submission of more than 240 proposals, 35% of which were funded, resulting in \$30 million for women's health research at UNC.

As we enter our second decade, we are revamping the direction for the Center. We are adopting business practices in much of our work, formalizing collaborations and partnerships, implementing plans to ensure our financial future, and aligning more closely with the goals and directions of the Office of Research on Women's Health (ORWH) at the National Institutes of Health (NIH). CWHR serves as UNC's liaison to the ORWH and is a lynch pin in the UNC women's health research network. We are a small, lean organization seeking to identify and link existing efforts in women's health research with related work in other fields, bringing multiple perspectives to bear on the complex issues inherent in studying and understanding women's health and wellness. We are mining data on current research efforts, identifying gaps and areas of opportunity, discovering new avenues for exploration, mobilizing the research community to develop ways of addressing the gaps and opportunities, and facilitating new areas of research.

Results from our data mining indicate that UNC is doing excellent work in select areas of women's health such as perinatal health and breast cancer; however the research agenda needs to reflect an expanded concept of women's health across the lifespan. Our research needs to be more inter- and trans-disciplinary. We need to adopt and implement the broader vision of women's health that calls for "...increasing our understanding of the role of sex/gender factors in differential disease risk, vulnerability, progression, and outcome, as well as the effects of being female on health..." (ORWH: Moving into the Future with New Dimensions and Strategies) as explicitly outlined by the Office for Research on Women's Health. Such an approach can and will benefit both women and men.

The ensuing pages outline our plan for the direction of the Center for the next ten years; italicized text indicates specific plans that are currently in place. By the end of this decade, we believe we will have made significant contributions to improving the health of women through research. We will focus on incorporating sex and gender differences in basic sciences research, to the benefit of both women and men. We will facilitate the translation of knowledge gained into viable clinical applications and influence the development of individualized medical approaches for women and girls. Through our efforts it will be easier for women's health investigators to link with others who are working on similar issues from different perspectives, so they can pose and pursue new research questions. And finally, we will increase the amount of grant dollars that are coming to the University for research in the field of women's health and wellness, bringing the UNC campus to national prominence in women's health research. This vision guided us as we developed this plan; we hope you will join us in sharing our vision and working with us to achieve it.

Wendy R. Brewster, MD, PhD
Director, Center for Women's Health Research at UNC

II. Mission, Historical Overview and Future Direction

MISSION

The mission of the Center for Women's Health Research (CWHR) 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

HISTORICAL OVERVIEW

The Center has been involved with more than 240 proposals to organizations such as the National Institutes of Health (NIH), the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC) and other federal agencies, private foundations, and multiple pharmaceutical companies conducting clinical trials. Today, an average grant submitted to one of the institutes of the NIH has less than a 15% chance of being funded; the average funding rate on proposals with which we have been involved has been approximately 35% overall.

For the past ten years we have produced and distributed the NC Women's Health Report Card biannually; it has been an in-depth review of the health status of North Carolina's women using a five-year rolling window for comparison. In 2011 we will shift to tracking ten-year trends in the major areas of research focus for the Center, more clearly tying the report card into the research agenda we are developing.

FUTURE DIRECTION

Because the field of women's health is extremely broad, we have adopted five topical areas to help focus research efforts over the next ten years:

- Perinatal health
- Cancers affecting women
- Obesity and diabetes
- Women's cardiovascular health
- Women's mental health and substance abuse

Using these topics we have classified funded research at UNC for calendar year 2009. Results clearly indicate a need to broaden the vision for women's health research at UNC, which we have incorporated as one of the cornerstones in our planning process.

As the concept of women's health research expands, we will encourage the development of innovative areas of research and areas that may not currently be defined, building on new discoveries and collaborations and adding new areas of focus as indicated.

Over the next ten years, we intend to provide a focal point for women's health research efforts on campus, promoting an appreciation and understanding of the importance of incorporating sex/gender differences into ongoing research, and further stimulating scientific endeavors within, among, and across all Schools, Colleges, Centers and Institutes at the University of North Carolina. This will help ensure that the research

enterprise at UNC continues to be vigorous and dynamic. Furthermore, we believe this plan is a tool for energizing 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.

The Center's mission will remain as stated earlier, but we are re-focusing our strategy, tactics and goals to more closely align with those of the National Institutes of Health and specifically with the ten-year strategy put forth by the Office of Research on Women's Health. To this end we propose that the Center be responsible for the following:

1. Serving as the official UNC liaison to the Office of Research on Women's Health (ORWH) at the NIH
2. Advising the UNC Vice Chancellor for Research and Economic Development and staff on matters relating to research on women's health and wellness
3. Ensuring that women's health research is an integral part of the framework and goals of the UNC research endeavor, and that priorities of the ORWH are incorporated into that framework
4. Strengthening and enhancing research related to diseases, disorders and conditions that affect women only, women predominately, or women differently than men
5. Serving as a focal point for NIH-funded research in women's health at UNC
6. Supporting existing/ongoing efforts to develop research opportunities for, and support the recruitment, re-entry, retention and advancement of women in their biomedical careers at UNC

III. Vision, Goals and Objectives

Our vision for 2011 through 2020 is to improve the health of all women through research by 1) focusing on sex and gender differences in basic sciences research, 2) facilitating translation of new knowledge into viable clinical applications and 3) influencing the development of individualized medical approaches for women and girls. Our efforts will enable women's health investigators to link with others who are working on similar issues from different perspectives, so they can pose and pursue new research questions. Our ongoing support of investigators will enhance the already collaborative environment at UNC and provide a coordination point for research activities in women's health and wellness.

GOAL 1 Maximize the impact of UNC's women's health research by creating strategic alliances and partnerships.

The Center for Women's Health Research is a small organization; we recognize that we could neither be large enough nor have sufficient expertise to work in all the areas of women's health and wellness that need attention. Therefore we propose to work through existing/emerging organizations within the University and in the larger community to advance the women's health research agenda. We do not intend to grow into a large organization but rather propose to partner extensively with others, serving as a lynch pin in an extended network of investigators and organizations for whom all aspects of women's health research are of ongoing interest. (See Appendix 1 for a timeline of specific plans for the first three years.)

Specific plans to contact organizations essential to furthering the women's health research agenda are being implemented . Targeted organizations include but are not limited to:

- *Key centers and organizations within UNC-Chapel Hill including the Office of the Vice Chancellor for Research and Economic Development, the TraCS Institute, all allied health schools and the College of Arts and Sciences*
 - *Initial talks were held with Interim Vice Chancellor Barbara Entwistle late in 2010; follow-up contacts per the conversation will be held in Q1 2011*
 - *Schedule a meeting with School of Medicine Vice Dean Marschall Runge during Q1 2011 to discuss the relationship of the Center with TraCS and to explore ways to work together*
 - *During Q2 2011, establish an agenda and schedule for meeting with deans of all allied health schools*
- *Other universities within the larger UNC system*
 - *Meet with the Dean of ECU School of Medicine to explore ways to jointly further the agenda of women's health research at ECU and UNC in 2013*
- *Organizations that effectively disseminate research information*
 - *Identify potential partner organizations during Q3-Q4 2011; make contact list and schedule meetings starting early 2012*
- *External organizations such as the NC General Assembly and the Women's Caucus*
 - *Meet with Kevin Fitzgerald during Q2 2011 to devise a plan for approaching the NC General Assembly and the Women's Caucus*
- *Multiple federal agencies including the NIH, HRSA, AHRQ and ORWH*
 - *Begin with the ORWH; Q2 2011, contact Joyce Ruddick to help us determine the most appropriate people in ORWH to contact*
 - *Schedule ORWH meeting no later than Q3 with Wendy Brewster and Carol Lorenz traveling to DC for a one-day meeting to discuss our use of the ORWH model and what being the liaison to ORWH could mean for UNC and ORWH, explore collaboration opportunities around the UNC Women's Health Research*

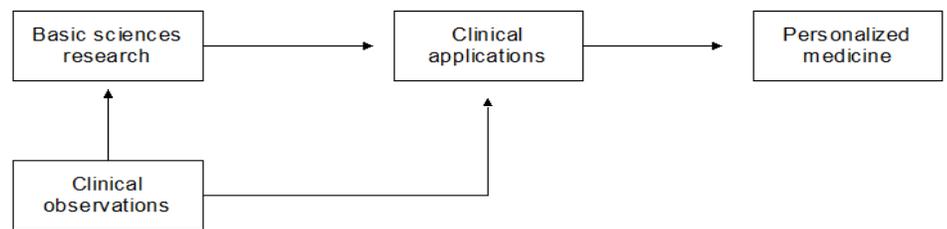
Academy and learn how ORWH approaches institutes and offices within the NIH

- Private organizations and foundations such as the American Heart Association, American Diabetes Association and the Mary Kay Foundation

GOAL 2 Enhance existing research efforts in all areas of women’s health and wellness by integrating the ORWH goals for research into the research agenda at UNC.

The Office of Research on Women’s Health has identified three broad areas as their focal point for women’s health research over the next decade: 1) biological sex differences research in **basic science** studies, 2) incorporation of findings into the design and application of new technologies, medical devices and therapeutic drugs (**clinical applications**) and 3) personalized prevention, diagnostics and therapeutics for girls and women (**personalized medicine**). A very simple diagram of this interaction is shown in Figure 1.

Figure 1. Interaction between sciences, clinical applications, and the development of personalized medicine



UNC has a tremendously collaborative environment with research being conducted in multiple scientific fields ranging from genetics to informatics and psychology to clinical work. However, our observation is that much of the inter- and trans-disciplinary research is happening largely by chance. Our purpose in proposing this goal is to establish linkages and information exchanges so that collaboration will begin to occur more by design and less by chance.

We propose to collaborate with the ORWH and begin the exchange of information by establishing a UNC Women’s Health Research Academy, which will be a formal network of clinicians and scientists working in women’s health and healthcare. We envision convening appropriate segments of the Academy around a series of women’s health “summit meetings” which will reflect the areas of research emphasis for the Center (perinatal health, mental health and substance abuse, obesity and diabetes, etc.), and bring together researchers from basic sciences and clinical areas to exchange information, explore applications and discuss implications for personalized medicine.

This goal will have several phases with Phases 1 and 2 being worked on simultaneously and Phase 3 positioned as a series of “summit meetings” to be held over the decade.

- *Phase 1: Identify what is currently being done with regard to the inclusion of biological sex in current research endeavors (research about the research) and engage investigators in conversations about their points of view, discuss possibilities and identify future paths for investigation.*
- *Phase 2: Engage clinicians/clinical researchers in conversations about their observations of clinical manifestations of diseases/disorders and conditions that affect women differently than men.*
- *Phase 3: Design and facilitate “summit meetings” in which basic scientists and clinical researchers come together to focus on implications of information from Phases 1 and 2. From these sessions, we will identify possible new areas for research, facilitate proposals for any areas that gain traction from the conversations, and include discussions around implications for personalized medicine approaches and what work would need to be done to bring the possibilities to fruition.*

To test the viability of this approach, the Center will pilot these three phases in two of our defined areas of research interest—obesity and women’s cardiovascular disease. Phases 1 and 2 will be complete by Q3 2011, with the initiation of the Women’s Health Research Academy and the first of the series of proposed “summit meetings” projected for Q2 2012. We will continually evaluate how well the process is working and document our ways of work so they can be duplicated in other areas as resources are available. We will document baseline activity in the two areas using ReachNC and RAMSeS and continue to track and monitor research activity levels throughout, using metrics such as the number of investigators in each area from which schools and/or departments, the number of inter- and trans-disciplinary proposals, number of proposals submitted, number funded and dollar amounts. We will develop a prototype of the Academy and involve the researchers in its formation, evaluation and evolution; the prototype will be scalable so that ultimately multiple areas of women’s health research can be included.

GOAL 3 Use the NC Women’s Health Report Card to monitor health trends and measure long-term improvement in the health of North Carolina’s women.

For the first decade of its existence, the NC Women’s Health Report Card documented the health of North Carolina’s women using short term measures; in 2011 we will begin using ten-year trends. Measured trends will reflect areas of research emphasis for the Center and will compare North Carolina results to national trends in the same areas. Results of the Report Card will influence the Center’s points of research emphasis. We are currently developing a ten-year plan for the evolution of the report card to track closely with this long range plan for the Center; the plan will include strategies to use Report Card macro data to help define the women’s health research agenda over time.

For the 2011 Report Card we envision the following timeline:

- Q1—complete data compilation
- Q2—review data and decide what to include; decide on layout and distribution plan
- Q3—release of the 2011 Report Card
- Q4—ten-year plan for NC Women’s Health Report Card complete

GOAL 4 Ensure financial stability for the Center beyond 2013.

To date, the Center for Women’s Health Research has been supported by start-up funds from the Department of Obstetrics and Gynecology, the Lineberger Comprehensive Cancer Center (LCCC), and the School of Medicine (SOM) Dean’s Office. Within the past three years, the Center has created a small revenue stream by administering grants. Over the past two years we have adopted a business-oriented approach, clarifying the services we offer and documenting the process for accessing our services and the process for grant submission through the Center. We have implemented a project tracking system to report the utilization of their investment to our funding sources, and to compare our cost of providing services to the return from grant administration revenue. We have made intermittent attempts at cultivating donors for the Center but have met with minimal success. We recognize our need to create additional revenue streams prior to 2013 and will define and pursue multiple avenues to achieve financial stability.

Action items for 2011 include the following:

- *Generate more indirect dollars coming into the Center by increasing the number of grants for which the Center is the administrator*
 - *As of July 1, 2010, the portfolio of grants and contracts that we administer stands at \$3,049,433; our target for this portfolio is \$10 million, which we project achieving by 2015*

- *Negotiate for extensions of contributions from existing funding sources beyond 2013*
 - *In Q1 2011, meet with the Department Chair of the Department of Obstetrics and Gynecology, Dan Clarke-Pearson, to discuss the extension of funds for the business office position, which expire June 30, 2011*
 - *Every six months (January and June) use the project tracking system to generate reports of how dollars from our three primary funding sources were spent; ensure reports are given annually to leaders of those organizations and hold follow-up meetings to ensure they understand how their contributions are being used. In Q3 2011 we will begin negotiating for continuation of these funds past 2013.*
- *Develop new sources of revenue*
 - *Establish a viable clinical trials unit*
 - ◆ *This is a business development effort; a business plan and processes for the implementation have been written and a position created to hire an individual to lead this program. We plan to have the individual in place by May 2011; the individual will be charged with seeking out and bringing appropriate clinical trials to the center. Our expectation is that by Q2 2012 the Center will be realizing a small revenue stream which we will re-invest in the Clinical Trials Unit to expand and increase our revenues over time.*
 - ◆ *Conduct financial reviews of ongoing clinical trials, provide information to the PI and to the Center Director and take appropriate actions as indicated by the reviews*
 - *Approach appropriate corporations and foundations through work with the Central Development Office*
 - ◆ *Identify agencies with whom they work and review for possible matches to Center needs*
 - *Pursue state funding at the appropriate time by working through the UNC Legislative Liaison*
 - ◆ *Schedule a meeting with Kevin Fitzgerald during Q1 2011 to develop a plan and approach*

GOAL 5 Support existing efforts to advance the careers of women in biomedical fields at UNC.

The foundation for progress in the sciences must be comprised of the brightest talent equipped with essential scientific knowledge and appropriate training. Although women are well represented in early phases of the life sciences, there is a widely recognized underrepresentation or absence of women in senior research leadership positions. It is essential to learn from and expand upon successful efforts and develop and implement innovative programs and policies that will attract, retain and advance women throughout their scientific careers. (Moving into the future with new dimensions and strategies, ORWH, September 2010)

UNC is no exception to the above statement from the ORWH; this is especially true in the School of Medicine where more than 50% of incoming medical school classes are female, but the leadership structure within the medical school remains predominately male. A contributing factor to this situation is the feminization of fixed-term faculty. About 60% of the total faculty is fixed-term while 74% of women faculty members are fixed-term. We recognize that there are efforts currently in place to begin addressing these issues so we propose that the Center partner with the appropriate individuals appointed by the Dean's Office to support a coordinated plan of action. The Center has limited resources to work on this goal but has group facilitation skills and the ability to identify and document processes which we will offer as our contributions.

GOAL 6 Increase understanding and appreciation of all aspects of women's health and wellness research through the use of new communication and social networking technologies.

Effective communication of information learned from research as well as opportunities for involvement in advancing the women's health research agenda need to be shared with diverse groups of people. Audiences that we need

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to reach include potential partners in research, care providers, potential funders and women/girls themselves. While we are limited in this area by our size and resources, in recognition of the cultural diversity, wide age range and breadth of our audiences, we will employ multiple strategies to have the greatest impact possible and tailor our messages to specific audiences. In areas in which we have limited expertise and resources, such as in the dissemination of research results, we will seek out organizations to partner with us in accomplishing our objectives.

IV. Resources

The Center is a remarkably efficient organization. In a total budget of \$7 million, only 3% is not covered by grants or contracts. Our goal is to keep the non-grant-funded portion of our budget at 5% or below while substantially increasing the amount of grant dollars we attract to the University by fully implementing this ten-year plan.

We will identify missed opportunities by conducting “research about the research”. This can be done at minimal cost; the tools to do the research exist in ReachNC and RAMSeS. We have developed a grid that crosses the ORWH priorities with the CWHR areas of research focus (Appendix 2) and have experimented with using ReachNC and RAMSeS to identify who is doing what in some of the cells. We already know from this very cursory look that there are many missed opportunities. Continuation and expansion of this work is an essential building block in this ten-year plan.

PROJECTED RESOURCE NEEDS

The Center will make an initial investment in the realization of this plan using existing resources. We will conduct in-depth “research about the research” in two areas—obesity and women’s cardiovascular health—to determine specific tasks required, develop and document the process and develop/implement a prototype of the Academy which can be expanded as additional resources are available. In the one to three year timeframe, we will need an investment of salary support for one experienced PhD level individual (about \$125,000 plus benefits) and one master’s level research assistant/project manager (\$45,000 plus benefits) to do the research in ReachNC and RAMSeS, establish and oversee the Academy and monitor progress toward Center goals. The PhD-level individual is currently in place at the CWHR; full salary support for this individual and the addition of a research assistant would enable the CWHR to develop and implement an operational approach to realizing elements of the proposed plan beyond the three-year window.

RETURN ON INVESTMENT

The potential payback to the School of Medicine and to the University in terms of identifying previously unexplored areas of research and generating grant proposals to respond to the gaps is large, and could be realized within two to three years. Because the CWHR has an infrastructure in place to provide strong internal support to the development and submission of proposals in the area of women’s health, and since the resulting work would be closely aligned with priorities of the NIH, the chances of obtaining funding would be increased, resulting in more research dollars for the Center, the SOM and the University.

V. Summary

We have an exciting decade ahead of us; CWHR will transition from being a young organization reacting to the issues in women's health to a mature one that is helping to define the agenda for research. The objective of improving women's health through research will be institutionalized across multiple disciplines, paving the way for great inter- and trans-disciplinary endeavors. **As a result of our work, researchers will find it easier to learn what others in the field or in similar fields are doing and to build collaborations with them. We will create opportunities to meet, network, collaborate and together advance the women's health research agenda.**

We will identify missing information about women's health and assist researchers and clinicians in making the connections, thereby opening new areas for research. Our goal is to have every research endeavor in which it is applicable consider the role of biological sex and/or gender differences in their research design. We will facilitate the translation of research findings into clinical applications and encourage discussions of the implications for personalized medicine for women and men.

We will strengthen the measurement of the long term improvement in women's health by revamping the NC Women's Health Report Card to monitor ten year trends, and use the data from this macro view of women's health in North Carolina to help define the women's health research agenda. We will conduct "research about the research" to identify gaps in UNC's current portfolio so the University has the opportunity to be a leader in new and emerging areas. And we will increase the awareness and understanding of all aspects of women's health and wellness through the use of new communication strategies and technologies.

The Center will remain a small organization working as the lynch pin in an extended network of investigators and organizations for whom all aspects of women's health research are an ongoing interest. We will work closely with the Office of Research on Women's Health to ensure we are aligned with the national agenda, and will develop mechanisms to provide input from UNC to the ORWH. As part of that national agenda, we will work to ensure the career advancement of women researchers in the biomedical fields.