Newton-Wellesley Hospital's

Oncology Research News

Newsletter from the Office of Research ■ Spring 2011

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Content:

CITI Collaborative Institutional Training Initiative
www.citiprogram.org

All investigators and research personnel participating in the conduct of human-subject research must complete the basic education program developed by the Collaborative Institutional Training Initiative (CITI).

The CITI program is comprehensive and provides case-based learning of ethical concepts and regulations in a web-based learning environment.

The **Basic Course** (for new personnel) is the first course to complete.

Once you have completed the **Basic Course,** all researchers and their staff are required to complete the CITI **Refresher Course** every three years.

Newton-Wellesley Hospital
Office of Research
2014 Washington Street
Ellison Hall 2nd Floor
Newton, Massachusetts
02462

Hope Violette, Manager Email

Https://www.nwh.org/cancer-trials

AAHRPP
Association for the Accreditation of Human Research Protection Programs, Inc.

AAHRPP
Enhancing Protections for Research Participants

AAHRPP offers accreditation to research organizations that provide comprehensive protections to research participants.

NWH Receives Reaccreditation of its Human Research Protection Program

The Newton-Wellesley Hospital Human Research Protection Program receives reaccreditation through the Association for Accreditation of Human Research Protection Programs (AAHRPP). Accreditation has been granted for a 5 year period.

Accreditation benefits everyone who contributes to research and development, by requiring them to constantly monitor their human research protection programs, so that they can quickly identify and address any weaknesses and build on their strengths.

The result is more cohesive, efficient, and effective research programs, with systems in place not only to protect research participants, but also to advance high quality science.

Some of the strengths of our program that were identified by Site Visitors were:

- The level of "confidence, competence and commitment" of every individual they interviewed
- Leadership
- Optimization of resources - specifically the Clinical Trials Program
- Facilitative approach to support of researchers
- Level of collaboration with colleagues at Partners
- Quality and diversity of IRB - members are "articulate, knowledgeable, and passionate"
- Ability to handle difficult situations very well (i.e. issues of compliance and unanticipated events)
- Level of knowledge of researchers and research staff

Thank you to everyone that helped achieve reaccreditation

Newton-Wellesley Hospital's Office of Research is fully accredited by the Association of Human Research Protection Programs (AAHRPP).
AAHRPP accreditation confirms that standards for the protection of human study participants is paramount in clinical trial operations at Newton-Wellesley Hospital.

Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation

Oncology Research News is published quarterly by the Newton-Wellesley Hospital Office of Research and distributed via NWH email. Forward suggestions and correspondence to Judy Chow Email.

Study Updates

BREAST

CALGB 40502
(Breast - Metastatic 1st Line)
Randomized Phase III Trial of Weekly Paclitaxel Compared to Weekly Nanoparticle Albumin Bound Nab-Paclitaxel or Ixabepilone Combined with Bevacizumab as First-Line Therapy for Locally Recurrent or Metastatic Breast Cancer

DF# 08-360

CALGB 40601
(Breast – HER2-positive Neoadjuvant)
Randomized Phase III Trial Of Paclitaxel Combined With Trastuzumab, Lapatinib, Or Both As Neoadjuvant Treatment Of Her2-Positive Primary Breast Cancer.

DF# 08-370

CALGB 40603
(Breast - Triple Negative Neoadjuvant)
Randomized Phase II 2 X 2 Factorial Trial Of The Addition Of Carboplatin +/- Bevacizumab To Neoadjuvant Weekly Paclitaxel Followed By Dose dense AC In Hormone Receptor-Poor/Her2-Negative Resectable Breast Cancer.

DF# 09-260

DF 94-138
(Breast, Ovarian – Banking/Registry) ***Genetics and Other Causes of Cancer***
The REACH project collects risk factor information, blood and tissue specimens from patients and family members at high risk for breast and/or ovarian cancer. The data and specimen bank will be used as a resource to be shared with researchers working in the areas of breast and ovarian cancer risk, prevention and treatment.

DF# 94-138

DF 06-169 ***(Breast/Observational: QoL)***
Helping Ourselves, Helping Others: The Young Women's Breast Cancer Study

LUNG

CALGB 30704
(NSCLC – 2nd Line treatment)
A Randomized Phase II Study To Assess The Efficacy Of Pemetrexed Or Sunitinib Or Pemetrexed Plus Sunitinib In The Second-Line Treatment Of Advanced Non-Small Cell Lung Cancer.

DF# 08-144

COLON

CALGB 80405
(Colon – Metastatic)
A Phase III Trial of Irinotecan / 5-FU / Leucovorin or Oxaliplatin / 5-FU / Leucovorin with Bevacizumab, or Cetuximab (C225) for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum.

DF# 05-449

LYMPHOMA

CALGB 50501
(Lymphoma - Treatment)
A Phase II Trial Of Bortezomib and Lenalidomide For Relapsed or Refractory Mantle Cell Lymphoma

DF# 08-066

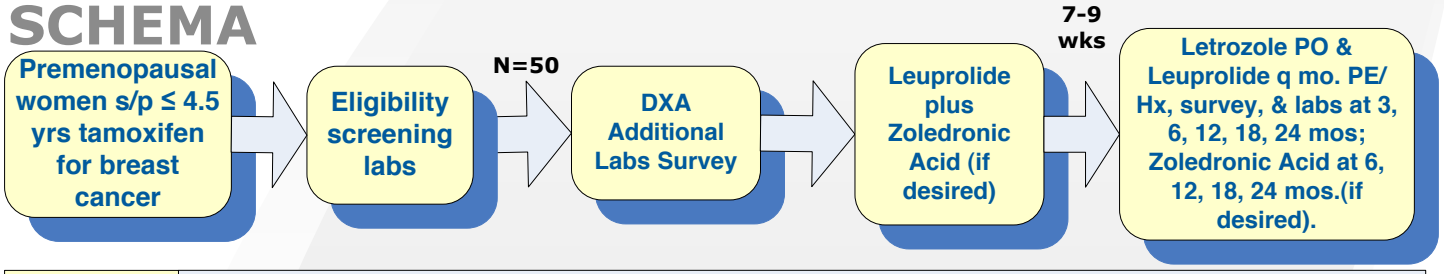
Source: Clinical Trials approved for participation at Newton-Wellesley Hospital, member of the Dana-Farber/Partners Cancer Care Affiliate Network.

Breast Cancer Study:
Phase II single-arm clinical trial

clinical trials.gov

Title: Extended Endocrine Therapy For Premenopausal Women With Breast Cancer

SCHEMA



Breast Cancer

OBJECTIVES

2.1 *Aim 1: TOLERABILITY*

Primary endpoint:

2.1.1 To determine the tolerability at one year of ovarian function suppression (OFS) using leuprolide (or eventual bilateral oophorectomy permitted instead) and an aromatase inhibitor (AI), letrozole, in women who remain premenopausal after tamoxifen therapy for early stage breast cancer. The primary outcome measure is what proportion of women discontinue AI or OFS due to symptoms or side effects by one year on study.

Secondary endpoint:

2.1.2 To determine what proportion of women discontinue AI or OFS therapy due to symptoms or side effects by two years on study.

2.2 *Aim 2: BONE HEALTH*

Secondary endpoint:

2.2.1 To explore the effect of ovarian function suppression (OFS) combined with aromatase inhibition combined with intravenous bisphosphonate therapy on bone mineral density in this population of premenopausal women previously treated with tamoxifen, as measured by median change in bone mineral density over time.

Exploratory endpoint:

2.2.2 To explore changes in serum markers of bone turnover with this regimen.

2.3 *Aim 3: SYMPTOMS*

Secondary endpoint:

2.3.1 To evaluate the effect of OFS combined with aromatase inhibitor therapy on the incidence and severity of menopausal symptoms, sexual dysfunction, musculoskeletal complaints, other side effects and overall quality of life in this population.

Exploratory endpoints:

2.3.2 To determine whether these symptoms correlate with levels of estradiol, estrone, and letrozole metabolites.

2.3.3 To explore relationships between health habits (including alcohol and tobacco use and exercise at baseline and over time) and the above outcomes of interest.

2.4 *Aim 4: Supplementary Safety and Compliance Monitoring:*

Secondary endpoint:

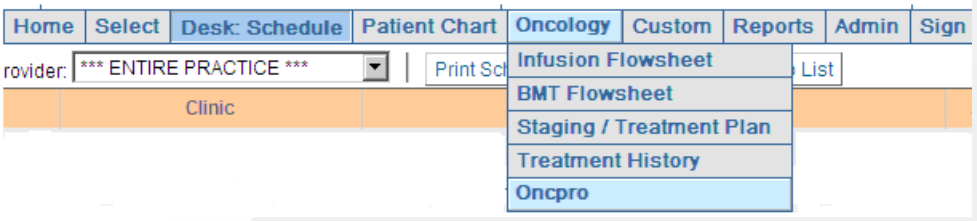
2.4.1 To measure degree of self-reported adherence to this regimen.

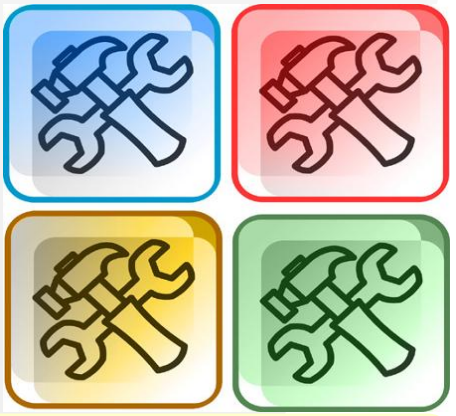
TOOLS & Training

Where To Find Protocols for CALGB and Dana-Farber Clinical Trials?

Protocols for Dana Farber and CALGB clinical trials open at Newton-Wellesley are available via the **Oncology Protocol System (OncPro)**
This application can be accessed through the Longitudinal Medical Record **(LMR)**.

Access OncPro from LMR
***From Main Toolbar*:**
***Select* ONCOLOGY drop-down tab, then OncPro**





OncPro User Guide

There are three ways to access the protocols in this system

Priority List: If you need to look up a protocol by disease, click on the priority list link. This gives you a listing by disease. The priority list has maximum of four levels of categorization for the protocols. You can click at any level to see all the protocols at that level as well as all the levels below it.

Protocol Index: To search for a protocol by year you can go to Protocol Index. The first 2 digits of a protocol number identify the year for the protocol. For instance:
For protocol 03-094 the year is 2003 (first 2 digits of 03-094)
For protocol 00-001 the year is 2000 (first 2 digits of 00-001)
You can also do a search by protocol number in Protocol Index.

Protocol Lookup: If you know the Principle Investigator(PI) for the protocol or you need to look up by the protocol number you can do it through the Protocol Lookup link. Type in the first few letters of the last name of the PI in the text box for the partial name lookup. This will bring up the name of the PI in the drop down box (Name List) below it(You can also look up the PI directly in the Name List drop down box). Then click on "Submit" to get all the protocols for that PI.

To learn more about eligibility and participation in clinical trials contact a member of our research team.

Oncology Research Nurse:
Kara Malcolm, RN
Phone: 617-243-5089 | Email

Oncology Research Coordinator:
Judy Chow, MM
Phone: 617-243-6392 | Email

Medical Director of Oncology Research:
Caroline Block, MD
Phone: 617-658-6000
Email

Office of Research Manager:
Hope Violette, RPh, CIP
Phone: 617-243-6493 | Email