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Award Number: DAMD17-00-1-0611

TITLE: Traditional Chinese Medicine Models and Epidemiological Approaches in Breast Cancer Diagnosis, Treatment and Progression

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REPORT DATE: October 2004

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

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20050407 151

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE October 2004	3. REPORT TYPE AND DATES COVERED Final (1 Sep 2000 - 1 Sep 2004)	
4. TITLE AND SUBTITLE Traditional Chinese Medicine Models and Epidemiological Approaches in Breast Cancer Diagnosis, Treatment and Progression			5. FUNDING NUMBERS DAMD17-00-1-0611	
6. AUTHOR(S) Marion M. Lee, Ph.D.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of California, San Francisco San Francisco, CA 94143-0962 E-Mail: mmllee@itsa.ucsf.edu			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited			12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 Words) The goal of this pilot study is to integrate traditional Chinese Medicine (TCM) to address breast cancer diagnosis, treatment and progression. It has been recognized that the heterogeneity of breast tumors makes treatment and prognosis debatable. TCM is based on the principle that illness is caused by an imbalance of chi, imbalance of yin and yang, or the deficiencies of dampness and dryness. In addition to a measurement of pulse and an inspection of the tongue, inquiries are made as to diet, exercise, meditation, sleep and environment. The TCM practitioner then arrives at a pattern-specific diagnosis. A total of 30 women with breast cancer were enrolled in the study and examined by the certified TCM practitioner at the Osher Center of Integrative Medicine of UCSF. Additional questions related to demographic, reproductive, family history, and lifestyle, were asked by the research nurse. Additionally pulses were measured using sphygmography and digital photography were performed to take tongue pictures. TCM data analyses classify TCM patterns into four distinct categories. We present data on the relationship between TCM patterns, predicting variables and breast cancer stages. Extending to larger sample, and a short and long-term follow-up on recurrence and survival are our future plans.				
14. SUBJECT TERMS Breast Cancer			15. NUMBER OF PAGES 27	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
298-102

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Final Report

TRADITIONAL CHINESE MEDICINE MODELS AND EPIDEMIOLOGIC APPROACHES IN BREAST CANCER

1. Introduction

The heterogeneity of breast tumors makes treatment decisions difficult. Different clinical patterns with the same stage may warrant different treatments and similar clinical features may also pose different prognoses. Traditional Chinese Medicine (TCM) offers a way to further classify breast cancer patients into different groups according to physical examination (pulse measurement, examination of body type, inspection of the tongue) and medical history (lifestyle, dietary habits, exercise habits, sleep pattern, emotional state, and other health problems). In general, TCM classifies patients into four groups: 1) Predominantly Yin deficient group; 2) predominantly Yang deficient group; 3) predominantly Qi stagnation group; and 4) predominantly damp accumulation group. This further classification has a potential to improve the current prognostic model of breast cancer survival. However, before we can undergo the prospective breast cancer survival study with the TCM classification, we need to devise a standardized TCM method to classify patients consistently.

The goal of this pilot epidemiologic study is to explore the feasibility of generating TCM classifications using a standardized method among women who were newly diagnosed with breast cancer in the San Francisco Bay Area. We believe results from this study will help provide insights into a new paradigm of breast cancer diagnosis, treatment and progression.

2. BODY

Rationale for the study design

The wide prevalence of use as well as the growing interest in TCM warrants a scientific evaluation of this modality. Though TCM has been used in China for thousands of years and has stood the test of time, it has not been thoroughly and rigorously evaluated according to Western scientific standards, and only until it has also stood up to the scientific rigor will it be accepted as a standard complement to Western medicine. This pilot study seeks to test the feasibility of formulating TCM classification of breast cancer using a standardized method. If successful, TCM classification formulated with this standardized method can be evaluated in a systemic scientific manner, and thus provide credibility to future TCM studies.

We do need to emphasize that this is a pilot study and is exploratory only, since to our knowledge, no similar study has been performed in the United States. We do not intend for this to be a large-scale reliability and validation study of TCM, nor do we intend for this to be a comprehensive or conclusive assessment of all aspects of TCM. Our main purpose of this study would be to test the feasibility of using the standardized method to make a TCM classification of breast cancer, using the classification by TCM practitioner as the standard for comparison. We will not be assessing the efficacy of any aspects of TCM in this study, but we do intend for this preliminary pilot study to provide the necessary information to pursue that means. A result from

this pilot study showing the feasibility of formulating TCM classification of breast cancer by the standardized method is necessary before we begin to address those issues in a larger study.

Outcome measures

The main outcome measure will be the four TCM categories mentioned previously. The outcome will be measured in two ways: 1) TCM practitioner assessment and 2) standardized method. In the TCM practitioner assessment, TCM practitioner will assign patients to one of the four TCM categories according to the result of the physical examination and medical history (see TCM practitioner intake form). In the standardized method, patients will answer pre-tested standardized questionnaires, have pulse measured by the sphygmography machine, and digital picture of the tongue taken for standardized characteristics (color, fur, sublingual vessels) analysis. The final TCM categories in the standardized method will be generated by a statistical algorithm (see statistical consideration in the material and methods section).

It should be noted that in this study, neither the assessment by the standardized method nor the assessment by the TCM practitioner diagnoses breast cancer, since the patient will already have an established diagnosis by her treating physician in the breast care center. The two methods of TCM assessment only sub-classify patients with established diagnoses.

Study subjects Eligible cases will be: (a) women between the ages of 30 and 79 who were diagnosed with histologically-confirmed primary invasive localized or regional breast cancer in the San Francisco Bay Area; (b) have no history of prior invasive or in situ breast cancer; (c) reside in one of the Bay Area counties: San Francisco, Marin, Alameda, Contra Costa, San Mateo, and Santa Clara at the time of diagnosis; (d) able to communicate in English; (e) able to consent for herself; and (f) are psychologically stable to participate in the study.

The intent of this study is exploratory and purely descriptive with no intent to generalize the findings to any target population. In addition, convenience sampling will be used to include consecutive eligible patients until we reach our target number of 30 patients. The target number has been modified from 60 to 30 based on our extensive recruitment efforts; and time and budget constraint.

Subjects recruitment

Our original recruitment site of UCSF Breast Care Center did not grant the permission for patient recruitment despite of the approval from the protocol review committee, two reasons were noted, one was because of the competing nature of this study with other on-going clinical trials; and the other reason was this grant does not provide compensation for the clinical staff in the Breast Care Center. We thus modify the recruitment methods from breast cancer support groups. A flyer was sent to support groups in the SF Bay Area and one of our nurse researcher presented the materials to the support group members and requested for participation in our study. The groups included Women's Cancer Resources Center of Oakland, East Bay Cancer Support Groups, Marin Breast Cancer Watch, CPMC Breast Health, St. Luck Breast Health and Chinese Joy Club. We emphasized to the patients during the recruitment process that participation in the study is voluntary. Patients are free to decline to be in the study or to withdraw from the study at any point even after they have signed the consent form. Breast cancer patients with no medical contraindication thus called our study office and scheduled an appointment to come to Osher Center for Integrative Medicine (OCIM) at UCSF to be interviewed and examined. Due to the

availability of our TCM practitioner's Friday appointment schedules, several interested subjects were unable to meet this particular appointment schedule, thus a few of them could not participate in our study.

Methods of data collection

Patients reported to OCIM at UCSF for the scheduled appointment. OCIM has provided a private room to be used by this study. Prior to beginning the study, the research assistant explained to the subjects about the study, the interview and the examination for the study, and the risks for participating in the study and to answer any questions subjects may have. If the subject agrees to participate, she then asked to sign an informed consent form and a medical release form allowing study personnel to abstract data from her medical record.

After the subject signed the informed consent, the data collection began with a 30-minute standardized interview by the research assistant, who recorded patient's answers on the standardized questionnaires titled "patient health questionnaire" and "confidential supplemental questionnaire. Information collected were family history of breast cancer, history of benign breast disease, dietary history, consumption of herbs, physical activity, and life events (see patient health questionnaire and confidential supplemental questionnaire).

After the standardized interview, subjects were placed on sphygmography machine for pulse measurement. The sphygmography machine is called ZM-IIIc Pulse Collector, which is produced by Scientific Development Company in collaboration with Shanghai University of TCM. The machine was kindly lent by Drs. Tom Wen and Yuan Chiu Lin. The machine has not been approved by FDA. A cuff would be placed on patients' wrist, with a pulse sensor applying minor pressure at the radial pulse. The sphygmography machine worked similarly to an electrocardiogram (EKG) machine, and the pulse measurements generated pulse wave graphs similar to those produced by the EKG machine.

After the completion of pulse measurement, digital photographs of patient's tongue were taken to assess the color, fur and sublingual vessels of the tongue (see tongue characteristic form). A digital camera would be placed in front of patient's face. She was asked to open her mouth and stick out her tongue straight and the top view of the tongue was photographed. The top view is for the observation of the shape, color, and the fur of the tongue. Next, patient was asked to lift her tongue and tilt her head back slightly for the photographing of the underside of the tongue. The underside view is for the observation of sublingual vessels. The digital photos would only include the image of the tongue. Patient's face would not appear in the picture, and any feature on patient's teeth or mouth that might personally identify her would be digitally removed from the photos.

Finally, subjects were examined by a certified TCM practitioner, Beverly Burns. Approximately 15 minutes is allowed for TCM examination, which consists of two components, interview, and physical examination. TCM practitioner first began by interviewing the patient about her general medical background, gynecologic and obstetric history, sleep pattern, and other physical illnesses that the patient has experienced (see TCM Practitioner Intake Form). Next, the TCM practitioner performed partial physical examination, which consists of inspection of body type, facial complexion, and tongue and feeling the radial pulses at both wrists. Patients would not have to disrobe for any part of the examination by the TCM practitioner. The TCM practitioner then

began the physical examination by observing patient's body type (tall, short, obese, skinny... etc) and patient's facial complexion (pale, red...etc). Then the TCM practitioner asked the patient to open her mouth and stick out her tongue to examine the body and coating of the tongue. The tongue is characterized by its color, texture, moisture, size and shape. Finally, the TCM practitioner would feel patient's radial pulses at both wrists. The pulses are characterized by the strength, rate, rhythm, and size. TCM practitioner then recorded her findings on the TCM practitioner intake form, which consists of both the interview and physical examination sections.

Although patients would answer similar questions asked by the interviewer and the TCM practitioner, this step was necessary because independent assessments by the standardized method and by the TCM practitioner are necessary for an unbiased comparison between the two methods. In addition, the TCM practitioner uses a more open-ended interview, where as questions in the standardized method are close-ended. The questions may be similar between the two methods, but the methods of obtaining the information are somewhat different.

In addition to collecting data through standardized TCM assessment and the examination by the TCM practitioner. The clinical data are limited to size of the breast tumor, regional lymph node involvement, metastasis and stages.

Data management Statistical consideration

A subject-tracking database was created using a Microsoft Access database program. Each subject was assigned a study identification number, starting with 01 and increase consecutively with each new subject. The data collected from the standardized TCM assessment, assessment by the TCM practitioner, and medical record abstraction were edited first by the study assistant for incomprehensible or incomplete answers, and then edited again by the project nurse researcher. The data were double entered into the computer by two different study members and consistency-checking program were used to find the discrepancies between the two data entries to reduce error.

The principal objective will be to assess the relationship between objectively measured patient attributes by the standardized method and the 4 major TCM diagnostic categories. Secondary objectives will be to assess the extent to which of the conceptual categories that underlie the TCM practitioner's assessment (e.g. pulse, tongue color, hot/cold diet prevalence, dietary preference, sleep and activity pattern and other characteristics) can be correlated with the relevant objective measures of the standardized method.

The following table gives the major TCM constructs and the corresponding objective measures:

TCM Domain	TCM Construct	Derivation of objective measure by the standardized method
Tongue	Color: red, pale, purple, yellow, white, purple red	Visual assessment of photograph & color chart
Tongue	Texture: with fur or not	Visual assessment of photograph
Pulse	Pattern: fine+rapid, slow+weak, wiry+tight, slippery+soggy	Pulse machine
Sleep	Restful or not	Questionnaire: hours spent in sleeping

TCM Domain	TCM Construct	Derivation of objective measure by the standardized method
Diet	Preference: stimulants, bitter sweet/salty, spicy, sausy	Diet questionnaire
Activity	Active or not	Questionnaire: exercise regularly
Body type	Slim/heavy	Personal questionnaire, BMI
Physical	Symptoms: constipation/diarrhea, fatigue, fever, cold hand etc.	Personal questionnaire on medical symptoms

Reimbursement

Each study participant was reimbursed \$30.00 in check for her time and effort. The check was issued by UCSF. According to the 2000 Occupational Employment Survey of California, the average hourly wage in San Francisco is about \$20.00. Taking into the consideration of the time travel to the study site (30 minutes), transportation and/or parking, and the time of participating in the study (60 minutes), \$30.00 would be an appropriate amount, which is also the amount given to patients in other similar studies at UCSF.

3. Key Accomplishment and Study Results

We have encountered so many problems related to this study. First the study was delayed for almost two years because of the UCSF IRB and protocol review committee's issues. We finally received the approval and began to plan the study last April. However, due to the budget constraint, we could not afford to hire a half time assistant, and had to compromise in hiring assistant in an hourly basis. The set back in patient recruitment was another drawback to the study. The actual field study did not begin until April 23, 2004. We had had a very hard time recruiting non-Asian women with breast cancer. We have relaxed the eligibility criteria because for those women recently diagnosed with breast cancer, they were too worry about their treatment options, they did not have energy to participate this kind of study. Other reason was due to the inflexible appointment scheduling at OCIM, our TCM practitioner only has appointments on Friday; some women could not make it especially on Fridays. Finally we ended up with 30 study subjects. The recruitment ended on September 14 of 2004.

On average, the age of diagnosis ranges from 40 to 76, with a mean age of 52.8.

11 subjects were Caucasian, and 19 subjects were Chinese and Asians.

95% of subjects were diagnosed at Stage I and II.

Mean age of menarche was 13.6 ranging from age 10 to 16.

20% (6/30) have gained weight, but 17% (5/30) have lost weight since diagnosis,

Marital status were as follows, 23% (7/30) were single, 50% (15/30) were married,

10% (3/30) were divorced, 10% were widowed and 7% were partnered with someone.

Two thirds had given births, and the average age of first birth was 29.7. 27% (8/30) had prior miscarriages and 43% (13/30) had abortions. 30% are currently having periods.

Majority (90%) were college graduates (27/30), only 10% attended high school or vocational school, currently 50% were unemployed.

Surprisingly, 27% (8/30) are currently smoking cigarettes, smoked less than 1/2 pack a day.

Only 36% (11/30) are never drinkers, however, if they drink, mostly drank less than 1 drink per week.

85% of the subjects now engage in regular exercise.

Ten of them considered themselves as "meat eater"; and none of them were vegetarians.

More than half (16/30) have taken oral contraceptive pills, and 20% had taken HRT.

One third of them have gone through psychotherapy or counseling, and are currently taking anti-depressant medication.

Two thirds of the subjects have a family history of cancer; one thirds' mother had cancer, 27% father had cancer, 20% grandparents have cancer, and 10% siblings have cancer.

Their past medical history reveals 5 ever suffered anemia, 3 with arthritis, 2 had asthma, 2 had bleeding problem, and 7 had depression or emotional problem, 12 of them had hay fever or sinus problem, 5 had hepatitis, 4 had thyroid diseases, 3 had high blood pressure, 2 had intestinal problem, and 5 had skin disease.

Half of the 30 subjects had chemotherapy, 16 had radiation therapy and 13 had hormonal therapy.

Facial complexion shows 20 of them were "good", and 18 of them had "enlarged" tongue; 12 were "normal" but 6 were "wet" and 10 were "dry". As to the color of the tongue, 23 were pale, 13 were white, 3 were red, and only 3 were normal.

As to the TCM categories, 9 women is predominately Yin deficient, and 11 of them are predominately Qi stagnation and 10 of them are predominately Damp accumulation. None of them belong to predominately Yang deficient. We further examine the characteristics for these three groups of women, but no particular factors stand out.

4. Discussion and Conclusion

We concluded that the feasibility of a study like this is possible. Note that this is a very select group of women with breast cancer who are interested in CAM; two thirds of them have ever received acupuncture treatment though it should not bias the validity of this study. However, there are a few issues are noted especially we would like to continue recruiting more patients but there is no financial support to continue the study. We have taken the tongue photos, but no one can help us to interpret the findings. I have a contact in Taiwan, Dr. Hong Chang, who is a MD and a CAM practitioner and had conducted a similar study in Chung Ken Memorial Hospital. I hope to bring the photos to him for interpretation at a later time. And because of the small sample size of 30, and lack of the tongue data, recursive statistically partitioning would not be able to perform. Additionally, because study subjects were recruited from different area and different hospitals, we were unable to obtain their medical records. Lastly the pulse machine is in an experimental stage, there were bugs in the computer program still need to be corrected.

5. Personnel received pay from the research effort

The principal investigator, Marion Lee, Ph.D., has extensive research experiences with breast cancer. Our TCM practitioner, Beverly Burns has a master degree in TCM and is a licensed acupuncturist. She has been a staff acupuncturist at UCSF/Mt Zion Breast Care Center since 1998. Judy Schwartz was hired in March 2004 to be our research coordinator, but she was

with the study for only two months. Julie Madsen is the research nurse, and Thoa Ngo is the research assistant.

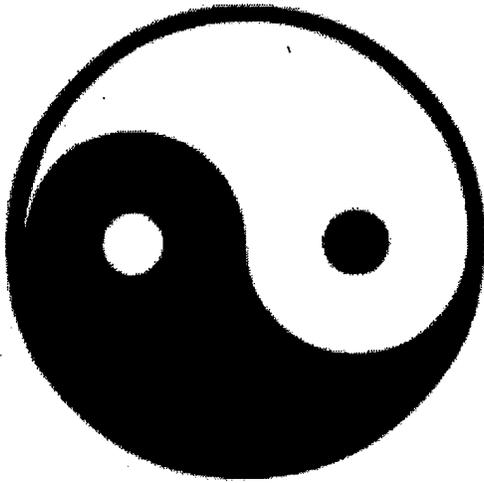
6. References

1. Beinfield Harriet & Korngold Efrem. *Between Heaven and Earth, A Guide to Chinese Medicine*. Ballantine Books, New York 1991
2. Shen Ziyin & Chen Zelin. *The Basis of Traditional Chinese Medicine*. Shambhala Publications, Inc., Boston & London 1996
3. Eisenberg DM, Davis RB, Ettner SL, et al. Trends in alternative medicine use in the United States, 1990-1997: results of a follow-up national survey. *JAMA* 1998;280:1569-1575.
4. Kessler RC, Davis RB, Foster DF, et al. Long-term trends in the use of complementary and alternative medical therapies in the United States. *Ann Intern Med* 2001;135:262-268.
5. Richardson MA, Sanders T, Palmer JL, Greisinger A, Singletary SE. Complementary/alternative medicine use in a comprehensive cancer center and the implications for oncology. *J Clin Oncol* 2000;18:2505-2514.
6. Lee MM, Lin SS, Wensch MR. Alternative therapies used by women with breast cancer in four ethnic populations. *J of Natl Cancer Inst* 2000;92:42-47.

7. Appendices

1. Study Flyer
2. TCM Practitioner Intake Form
3. Tongue Characteristics Form
4. Patient Health Questionnaire
5. TCM Study Pulse Form

Traditional Chinese Medicine Models and Epidemiologic Approaches in Breast Cancer



Dr. Marion Lee, Professor of the Department of Epidemiology and Biostatistics at UCSF is conducting a study involving Traditional Chinese Medicine (TCM). The goal of this pilot study is to examine the feasibility of making TCM classification among breast cancer patients using a standardized method. Women between the ages of 30 to 79, who are newly diagnosed with breast cancer, are eligible to participate in the study.

Participation in the study includes:

- 45-minute interview about lifestyle, diet, exercise, and family history, conducted by an experienced interviewer.
- Pulse measurement by the pulse machine.
- Digital photography of the tongue.
- 30-minute TCM examination by a certified TCM practitioner.

Participant will be reimbursed for \$50 as a token of appreciation for her time and effort.

Interested subject can call the study office at **(415) 476-3366** to arrange for an appointment.

**TRADITIONAL CHINESE MEDICINE MODELS AND EPIDEMIOLOGIC
APPROACHES IN BREAST CANCER**

TCM PRACTITIONER INTAKE FORM

NOTE TO THE TCM PRACTITIONER: FOR STUDY PURPOSES, PLEASE DO NOT ASK THE PARTICIPANT ANY QUESTIONS RELATED TO HER BREAST CANCER DIAGNOSIS OR HER TREATMENT.

A. GENERAL MEDICAL BACKGROUND

1. Have you ever received acupuncture? YES NO

If yes, when? _____

For what condition? _____

2. Are you allergic to any drugs or foods? YES NO

Please explain: _____

3. Is there a history of disease in your family? Y N

If yes, please explain: _____

4. Have you been treated for a prolonged illness, injury, hospitalization, etc.? Y N

If yes, please explain: _____

5. Were there any severe illnesses during your childhood, or complications during your birth? YES NO

If yes, please explain: _____

B. TCM QUESTIONS:

1. Do you experience chills or fever, or feel hot or cold? ___Y___N

If yes, please explain: _____

2. Do you sweat easily or profusely? ___Y___N Time of day? _____

If yes, please explain: _____

3. Are you thirsty often: ___Y___N Time of day? _____

If yes, please explain: _____

4. How is your appetite? _____

A. What is your taste preference? _____

B. What are your food preferences? _____

5. How is your sleep? _____

6. How are your bowel movements? _____

7. How is your urination? _____

8. How is your energy level? _____

9. How is your libido? _____

10. How are your emotions? _____

C. REVIEW OF SYSTEMS:

PLEASE NOTE IF THERE ARE ANY COMMENTS ABOUT THE FOLLOWING
(check box if negative):

Head	<input type="checkbox"/>
Ears	<input type="checkbox"/>
Eyes	<input type="checkbox"/>
Nose	<input type="checkbox"/>
Throat	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Respiratory System	<input type="checkbox"/>
Circulatory System	<input type="checkbox"/>
Digestive System	<input type="checkbox"/>
Genito-Urinary System	<input type="checkbox"/>
Neurological System	<input type="checkbox"/>
Musculo-Skeletal	<input type="checkbox"/>

D. GYNECOLOGIC HISTORY

1. Age at onset of menses _____
2. Please describe your menstrual flow: _____

3. Do you usually experience cramping? ___ Y ___ N
4. Do you experience premenstrual symptoms? ___ Y ___ N
If yes, please explain: _____

5. What is your current method of birth control? _____
6. Have you ever taken oral contraceptives? ___ Y ___ N
If yes, for how many years? _____
7. Have you passed menopause ___ Y ___ N
If yes: age of onset _____
age of completion _____
8. Did you experience severe menopausal symptoms? ___ Y ___ N
If yes, please describe: _____

9. Are you on hormone replacement therapy (estrogen)? ___ Y ___ N
If yes: How long have you been taking HRT? _____
What type? _____

**TRADITIONAL CHINESE MEDICINE MODELS AND EPIDEMIOLOGIC
APPROACHES IN BREAST CANCER**

TCM PRACTITIONER INTAKE FORM

FOR THE TCM PRACTITIONER TO FILL OUT:

(Please record descriptions in the space provided)

A. FACIAL COMPLEXION AND BODY TYPE

B. PULSE MEASUREMENT

C. TONGUE

D. TCM CATEGORIES

___ PREDOMINATELY YIN DEFICIENT

___ PREDOMINATELY YANG DEFICIENT

___ PREDOMINATELY QI STAGNATION

___ PREDOMINATELY DAMP ACCUMULATION

COMMENT ON SUB-CATEGORIES:

**Traditional Chinese Medicine Models and Epidemiologic Approaches
in Breast Cancer**

TONGUE CHARACTERISTICS FORM

A. Color

<input type="checkbox"/> 01 normal pink color <input type="checkbox"/> 02 pale <input type="checkbox"/> 03 red <input type="checkbox"/> 04 dusky <input type="checkbox"/> 05 deep red/purple <input type="checkbox"/> 06 red at the tip <input type="checkbox"/> 07 red at sides <input type="checkbox"/> 08 prickles <input type="checkbox"/> 09 other: specify _____
--

B. Texture

<input type="checkbox"/> 01 normal smooth fur <input type="checkbox"/> 02 thickened fur → → → <input type="checkbox"/> 03 mirrored coat <input type="checkbox"/> 04 other: specify _____	If thickened fur is present: Color: <input type="checkbox"/> 01 white <input type="checkbox"/> 02 yellow <input type="checkbox"/> 02 gray Location: <input type="checkbox"/> 01 entire tongue <input type="checkbox"/> 02 root of tongue <input type="checkbox"/> 03 center of tongue
--	---

C. Moisture

<input type="checkbox"/> 01 normal <input type="checkbox"/> 02 excessively wet <input type="checkbox"/> 03 dry <input type="checkbox"/> 04 other: specify _____
--

D. Size and Shape

<input type="checkbox"/> 01 normal size <input type="checkbox"/> 02 enlarged <input type="checkbox"/> 03 small <input type="checkbox"/> 04 scalloped <input type="checkbox"/> 05 other: specify _____
--

TRADITIONAL CHINESE MODELS AND EPIDEMIOLOGICAL APPROACHES

PATIENT HEALTH QUESTIONNAIRE

The following is a detailed questionnaire that asks about many areas of your health. Please respond as best as is possible. Should you have questions, please feel free to ask the study coordinator for clarification.

A. PAST MEDICAL HISTORY

1. Please check the appropriate box regarding any significant illness which applies to you:

Alcoholism	<input type="checkbox"/> YES	<input type="checkbox"/> NO	High Blood Pressure	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Anemia	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Immune Disorders	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Arthritis	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Intestinal Problems	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Asthma/Bronchitis/Emphysema	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Kidney Disease	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Bleeding/Bruising/Blood Disorder	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Liver Disease	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Depression/Emotional Problems	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Lung Disease	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Diabetes	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Psychiatric	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Drug Abuse/Alcohol Dependency	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Skin Disease	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Epilepsy/Seizures	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Stroke	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Hay Fever/Sinus Problems	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Stomach Ulcers	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Heart Problems	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Thyroid Disease	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Hepatitis	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Tuberculosis	<input type="checkbox"/> YES	<input type="checkbox"/> NO

Have you had cancer **other than** breast cancer? YES NO

If yes, what type of cancer and treatment did you have? _____

Other major illnesses (please describe): _____

2. Please list:

<u>Hospitalizations</u>	<u>Date</u>	<u>Prior Surgeries</u>	<u>Date</u>	<u>Serious Injuries</u>	<u>Date</u>
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

3. Have you had any prior breast surgery or biopsies? YES NO

If yes, please describe (Fine Needle Aspirate, Core Biopsy, Lumpectomy, Mastectomy, etc.)

<u>Location (Right/Left)</u>	<u>Procedure</u>	<u>Date</u>	<u>Result</u>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

4. Have you ever had breast cancer? YES NO

5. If you were diagnosed with breast cancer, did you receive other types of treatment for your breast cancer?
(Please list dates.) **If YES, dates:**

Chemotherapy	<input type="checkbox"/> YES	<input type="checkbox"/> NO	_____
Radiation Therapy	<input type="checkbox"/> YES	<input type="checkbox"/> NO	_____
Hormone Therapy	<input type="checkbox"/> YES	<input type="checkbox"/> NO	_____

6. List all current medications you are taking and their dosages (prescription, e.g. hormone replacement therapy, and all over the counter drugs):

7. Are you taking any vitamins or herbs? YES NO

If yes, please list: _____

8. List medication, allergies, and reaction type:

9. Do you exercise regularly? YES NO What type? _____

If yes, how often? less than 1x per week For how many minutes? _____

- 1x per week
- 2x per week
- 3x per week
- more than 3x per week

10. Have you undergone psychotherapy or counseling? YES NO

11. Have you been hospitalized for psychiatric reasons? YES NO

12. Have you taken medicine for depression, nervousness, or a psychiatric condition? YES NO

If yes, what? _____

13. Have you ever participated in a support group? YES NO

14. Please list what you eat for a typical meal:

Breakfast: _____

 Lunch: _____

 Dinner: _____

 Snacks: _____

15. Do you eat meat regularly? YES NO

16. Do you eat dairy regularly? YES NO

17. Please list the foods you crave regularly: _____

B. GYNECOLOGIC HISTORY

(If Male, please skip to Patient Social History section on the next page)

1. How old were you when you first menstruated? _____

2. What is the number of days between your periods?

- 01. Less than 21 days 02. 21 to 25 days 03. 26 to 28 days
- 04. 29-30 days 05. 31-35 days 06. > 36 days

3. At what age did you have your first period? _____

4. How many times have you been pregnant? _____

A. How many miscarriages have you had? _____

B. How many abortions have you had? _____

C. How many live births have you had? _____

D. Have you had a period within the last 6 months? YES NO
 If yes, is your period: Regular or Irregular

If no, this is because of:

- _____ natural menopause (no abdominal surgery)? Age _____
- _____ chemotherapy or radiation therapy? Age _____
- _____ pregnant or breastfeeding? Age _____

E. If you have given birth, what was your age at your first full-term pregnancy? _____

5. Have you had a hysterectomy? YES NO NOT SURE
 Date of surgery _____

6. Have you had any ovaries removed? YES NO NOT SURE
 Date of surgery _____

If yes: How many were removed: _____ One _____ Two

7. Do you, or have you ever used, birth control pills? YES NO NOT SURE

If yes, for how many years? (If less than one year, enter 1.)

number of years _____

beginning at what age _____

8. Have you ever used, or do you use, estrogen or estrogen replacement therapy?

No, never. (If NO, please go to question 11.)

Yes, currently.

Yes, in the past.

9. If you used estrogen currently or in the past, what form of estrogen do/did you use? Check all that apply:

Pill

Patch

Vaginal Cream

Other _____

10. How many total years have you used estrogen replacement? (If less than one year, enter 1.)

number of years _____

beginning at what age _____

11. What was the approximate date of your last pelvic exam (internal female exam)?

month _____ year _____

C. PATIENT SOCIAL HISTORY

1. What is your marital status?

Single

Married

Divorced

Partnered

Widowed

2. Who currently lives in your home? _____

3. Education level: Select one that best describes your education level:

Some grade school

Some college or associate's degree

Some high school

Undergraduate school

High school graduate

Graduate or professional school

Vocational or technical school beyond high school Other _____

4. What is your current occupation? _____

5. What is your current employment status?

Employed 32 hours or more per week

Part time student

Homemaker

Employed less than 32 hours per week

On medical leave

Retired

Full time student

Disabled

Unemployed

Other _____

6. Have you ever smoked?

- Yes, but only in the past.
- Yes, currently.
- No, never.

If yes: A. On average, how many packs per day did you or do you currently smoke?

- less than 1/2 pack per day 1 1/2 packs per day
- 1/2 pack per day 2 packs per day
- 1 pack per day more than 2 packs per day

B. At what age did you START smoking? _____ years old

C. At what age did you STOP smoking? _____ years old

7. Have you ever or do you currently drink alcohol?

- Yes, but only in the past. Yes, currently. No, never.

If currently yes: How many alcoholic beverages (beer, wine, mixed drinks, etc.) do you consume weekly?

- less than 1 drink per week 10-19 drinks per week
- 1-4 drinks per week more than 19 drinks per week
- 5-9 drinks per week

D. FAMILY HISTORY

Please take a moment to tell us about the history of cancer and other medical conditions in your family. Use our list of cancer types below as a reference for "Type of Cancer".

Types of Cancers:

Bladder/Kidney	Invasive Cervical	Lymphoma	Ovarian
Breast	Leukemia	Melanoma	Thyroid
Colorectal	Lung	Mouth/Throat	Uterine

RELATIONSHIP	TYPE OF CANCER	OTHER MEDICAL CONDITIONS	AGE AT DIAGNOSIS	AGE AT DEATH (if deceased)
Mother				
Father				
Sister				
Sister				
Brother				
Brother				
Daughter				
Daughter				
Son				
Son				
Maternal Grandfather				
Paternal Grandfather				
Maternal Grandmother				

Paternal Grandmother				
Other _____				

E. REVIEW OF SYSTEMS

Please mark if you have experienced any problems or symptoms in the following areas. Indicate if it is current or in the past, and **please include dates when appropriate.**

	Current	Past	Comments:
<u>Constitutional</u>			
A. Recent weight changes			
B. Recurrent fevers, chills, sweats			
C. Fatigue			
D. Stress			
E. Pain			
<u>Eyes</u>			
A. Change in vision			
B. Glaucoma			
<u>Ear/Nose/Mouth/Throat</u>			
A. Change in hearing			
B. Ringing in the ears			
C. Nose bleeds			
D. Sinus problems			
E. Mouth sores			
F. Bleeding gums			
G. Frequent sore throats			
<u>Respiratory</u>			
A. Asthma or wheezing			
B. Shortness of breath			
C. Chronic cough			
<u>Cardiovascular</u>			
A. Chest pain or angina			
B. Palpitations			
C. Swelling of feet, ankles or hands			
D. Varicose veins			
E. Cold hands and/or feet			
<u>Gastrointestinal</u>			
A. Change in appetite			
B. Ulcers			
C. Nausea/vomiting			
D. Diarrhea			
E. Constipation or painful bowel movement			
F. Rectal bleeding			
G. Abdominal pain			
H. Hemorrhoid			
<u>Neurological</u>			
A. Headaches			
B. Numbness or tingling sensations			

C. Weakness or paralysis			
D. Change in memory or concentration			
	Current	Past	Comments:
<u>Genitourinary</u>			
A. Blood in the urine			
B. Burning with urination			
C. Change in force of urine stream			
D. Sexually transmitted disease			
E. Change in sexual function or interest			
F. Pain/problems with periods			
G. Uterine tumors			
H. Abnormal uterine bleeding			
I. Prostate trouble (men)			
J. Scrotal masses (men)			
<u>Integumentary (skin & breasts)</u>			
A. Recurrent rashes			
B. Changing moles			
C. Skin cancer or melanoma			
D. Non-healing wounds			
E. Change in hair or nails			
<u>Psychiatric</u>			
A. Memory loss or confusion			
B. Nervousness			
C. Depression			
D. Change in sleep			
E. Other			
<u>Musculoskeletal</u>			
A. Joint stiffness or pain			
B. Muscle pain or cramping			
C. Weakness of muscles or joints			
D. Back pain			
E. Difficulty walking			
<u>Endocrine</u>			
A. Heat or cold intolerance			
B. Excess thirst or urination			
<u>Allergic/Immunologic</u>			
A. Frequent cold or flu			
B. Environmental allergies			
C. Food Sensitivity			
<u>Hematologic/Lymphatic</u>			
A. Easy bruising			
B. Enlarged lymph nodes			

F. DEMOGRAPHIC QUESTIONS (Optional)

1. Race/Ethnicity:

- Caucasian/White
- African American
- American Indian, Aleutian or Eskimo
- Asian or Pacific Islander
- Unknown
- Other (please specify): _____

2. Are you of Spanish or Hispanic Origin? Yes No Unknown

3. Are you of Ashkenazi Jewish Descent? Yes No Unknown

1. In case our office needs to call you for further information, when is a convenient time to reach you?

Best Time _____ AM/PM

Address _____

Phone Number _____

2. Is there someone whom we may contact in case we need to reach you in the future? What is his/her name, address and phone number? What is his/her relationship to you?

Name _____ Relationship _____

Address _____

Phone Number _____

Your participation in this study is greatly appreciated. Should you have any questions and/or comments, please feel free to speak with the study coordinator.

The number of the **Cancer Information Service** is 1-800-4CANCER.

Thank you for your participation.

Pulse Position	Pulse Strength
Pulse Fluency	Pulse Rate
Pulse Rhythm	Pulse Form
Pulse Name	

Pulse Position	Pulse Strength
Pulse Fluency	Pulse Rate
Pulse Rhythm	Pulse Form
Pulse Name	