Request for Approval under the
"Generic Clearance for the Collection of Routine Customer Feedback" (NIH/OER)
(OMB Control Number: 0925-0648-1, Expiration Date 1/31/2015)

TITLE OF INFORMATION COLLECTION: Requirements Gathering for Patient-Centered Communication (PCC) Web-based Application for NCI

PURPOSE: This project seeks to develop a web-based and cancer-based patient-focused system with the goal to facilitate communication and care for cancer patients. The computer program/website is being developed to ease anxiety and psychological distress related to the cancer diagnosis and treatment. In order to develop the website, an assessment of the type of information is needed, the best ways to provide that information, what can help people make informed decisions, and what we can do to empower patients in their care experience. The website will provide the patient with a wealth of information and capabilities, such as: calendaring tools to keep track of treatment schedules and events; symptom assessments that enable symptom tracking over time and sharing this with their oncologist; educational materials; clinical trials; and decision aids. There is also a social networking function that: allows the patient to invite their friends and family to interact and support him/her during the cancer journey; allows local support groups and recognized support organizations to post events that, if applicable, are presented to the patient; and provides the oncology care team with a way to receive symptom alerts and communicate with the patient. The overall idea is that by tying in all of these components into one system, the patient will empowered by the ability to quickly and easily access support and information relating to their cancer care. There are two phases, the initial phase is a requirements gathering phase to understand the expectations and needs from the patients, providers, caregivers and support leaders. The second phase involves usability testing to confirm the application meets the needs of the users.

Requirements Gathering – Phase 1
The initial step in this process is gathering the requirements relating to expectations and needs from the patients. The pre-development and development stages of the system require the input of patients and those in direct contact with patients (providers, caregivers, and support resource leaders such as promotoras and support group leaders). Group and individual interviews (with providers) will be conducted in order to determine the preferred new cancer-specific content for the Phase II software, as well as system features specific to each different person's role. The discussion topics of the interviews will be on issues related to desired system functionalities, user interface design and overall system usefulness. The specific tasks include the discussion of what functionalities they may expect from such a system, the review of Phase I prototype, and the explorations of the prototype's strengths and limitations.

DESCRIPTION OF RESPONDENTS:
Group Interviews. Four 60-minute group interview sessions will be convened to solicit input from (1) patients who have recently been diagnosed with cancer and just started treatment; (2) caregivers or family members of patients who have recently started cancer treatment; (3) members of local support groups and organizations for cancer patients; and (4) promotoras experienced in assisting cancer patients. All groups will have up to nine subjects.

Individual Interviews. Similarly we need to solicit feedback from cancer care team members, including oncologists, nurses, and specialists. Instead of conducting a group interview, we plan to conduct 9 individual interviews with members of the care team for their input to avoid scheduling difficulties due to their busy schedules.

TYPE OF COLLECTION: (Check one)

[ ] Customer Comment Card/Complaint Form [ ] Customer Satisfaction Survey
[ ] Usability Testing (e.g., Website or Software [ ] Small Discussion Group
[ ] Focus Group [X] Other: Group and Individual Interviews

CERTIFICATION:
I certify the following to be true:
1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does <u>not</u> raise issues of concern to other federal agencies.
4. The results are <u>not</u> intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of <u>substantially</u> informing <u>influential</u> policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: DerShung Yang

To assist review, please provide answers to the following question:

Personally Identifiable Information:
1. Is personally identifiable information (PII) collected? [X] Yes [ ] No
2. If Yes, will any information that is collected be included in records that are subject to the Privacy Act of 1974?   [X] Yes [ ] No
3. If Yes, has an up-to-date System of Records Notice (SORN) been published? [X] Yes [ ] No

Gifts or Payments:
Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [X] Yes [ ] No

The participants in the group interviews (patients, caregivers, support group leaders and promotoras will be compensated $20 and the providers will be compensated $30. This compensation is meant to offset the financial burden associated with time spent, travel, and miscellaneous expenses related to attending the group and individual interviews.

BURDEN HOURS

Category of Respondent	No. of Respondents	Participation Time	Burden
Individuals	45	60 minutes	45 hrs
Totals	**45**		**45 hrs**

Total Burden Hours used for IC's to date: 923
Total Burden Hours Approved for IC's under 0925-0648:   148,072
Total Burden Hours currently requested: 45

FEDERAL COST: The estimated annual cost to the Federal government is __$5,000_____

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents
1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?
                                                    [ ] Yes [X] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)?   If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

The providers and participants will be identified and approached through a physician who collaborates with the contractor. The physician will consult the roster of patients to identify and approach those who may be interested and who qualify. The patients will be asked to talk with their caregivers about the interviews and refer them if interested. The caregivers may also be identified and approached by this physician from her clinical practice. The same physician will also identify support group leaders and promotoras that have had contact or worked with at the clinic in the past. The physician will start the initial contact to ascertain if the person is interested in participating in the group interview. If the person is interested, his/her contact information will be passed along to the project's UA-based research team who will then contact the person for consent and scheduling.

Administration of the Instrument
1. How will you collect the information? (Check all that apply)
        [ ] Web-based or other forms of Social Media
        [ ] Telephone
        [X] In-person
        [ ] Mail
        [ ] Other, Explain

2. Will interviewers or facilitators be used? [X] Yes [ ] No

List of instruments, instructions, and scripts submitted with this request:

Attachments 1-4: Phase 1 – Requirements Gathering
Attachment 5: Phases 1 and 2
Attachments 6-10: Phase 2 – Usability Testing

  Attachment 1: Moderator's Guide - Patient, Caregivers, Support Leaders and Promotoras
  Attachment 2: Moderator's Guide - Providers
  Attachment 3: Consent Form - Patient, Caregivers, Support Group Leaders and Promotoras
  Attachment 4: Consent Form - Providers
  Attachment 5: Mock Ups of Website
  Attachment 6: Patient Usability Protocol
  Attachment 7: Support Person Usability Protocol
  Attachment 8:   System Usability Study (SUS)
  Attachment 9:   Consent Form - Patient
  Attachment 10: Consent Form - Support People