OREGON COLLEGE *of* ORIENTAL MEDICINE

OREGON COLLEGE OF ORIENTAL MEDICINE
INSTITUTIONAL REVIEW BOARD
IRB Questionnaire (IRBQ)
(To be submitted with the complete research proposal)

Date 8/12/09

Principal Investigator: **Tim Chapman, Ph.D.**

Phone: 503-253-3443 x 136 Affiliation w/OCOM: **Vice President for Academic Affairs**

Email address: **tchapman@ocom.edu**

Additional study personnel (name, title, role, contact information, affiliation with OCOM)

Robert Kaneko, Dean of Clinics; Beth Burch, Dean of Doctoral Studies; Zhaoxue Lu, Chair of AOM/Doctoral Program; Rosa Schnyer, past chair, OCOM Clinic Research Committee

Proposal Title: **Systematic Assessment of Patient Reported Outcomes in the OCOM Acupuncture and Herbal Clinic**

Funding Source: (list all that may apply) **Internal OCOM funding**

Study type: ___ Prospective interventional (e.g., clinical trial) ___ Retrospective chart review
___ Secondary data analysis only **X** Other (specify)

Systematic prospective collection of patient reported outcomes.

1. ***Abstract of Proposal*** *(Summarize the objectives and procedures of the project in lay terminology in 150-300 words)*

Approval is sought from the OCOM IRB for modifications to the current OCOM Acupuncture and Herbal Clinic informed consent and patient health history forms. These forms are completed by all incoming (new) patients treated in the main OCOM clinic and its directly-overseen satellite clinic at Hollywood Square. Patients

also complete a 5th treatment follow-up form. The proposed time-frame for implementation of the revised forms is mid-September 2009, which coincides with the start of the clinical experience for a new incoming intern group. Derived from pre-existing instruments (with some new additions), the forms have been reviewed and revised over the past six months via an iterative process overseen by the OCOM Clinic Research Committee (CRC). Where feasible, the CRC process has incorporated input and suggestions from OCOM faculty, clinic administrators, and clinic reception staff. In addition to the form revisions, IBR approval is sought for a proposal to integrate the data collected from the forms into current OCOM patient medical record databases. The overall goals of this project are: 1) to enhance the validity and reliability of OCOM's patient outcomes data, encouraging improvements in the quality of care current patients receive; and 2) to develop a systematic infrastructure of data collection that will facilitate a wide range of future patient reported outcomes -based research investigations at OCOM.

2. **<u>Sites/Subjects</u>**

Site(s) where research will be conducted:

Internship sites directly overseen by OCOM. Currently includes the main OCOM campus clinic and the Hollywood Square clinic.

Estimated number of subjects from OCOM: **1,750 annually**

Total number for project: **1,750 annually**

Characteristics of subjects: (check all that apply)

X Adults _____ Healthy Volunteers Sex: F X M X

Age range: **18 and over**

Special Subject Categories (check as needed):

Children _____ Subjects who may be incompetent _____ Prisoners _____

If any of the above categories are checked, how will you assure they protected?

_____

Source of Subjects: (clinic, general public, etc.)

New patients entering OCOM internship clinics.

Please describe how subject will receive Consent information:

Practitioner will go over informed consent form in detail with all new patients to ensure adequate understanding.

3. <u>Herbs/Devices</u>

Will Herbs be used? ___ Y ___ N If yes, name of herb(s) and company:

NOT APPLICABLE

Form of the herbal formula: ____raw herbs ____ granules ____ patents

Explain how the formula was determined & how herbs will be administered (capsules, tea, etc)

Will a medical device be used? ___Y ___N Is it an investigational device? ___Y ___N

Name of device and manufacturer:

NOT APPLICABLE

4. <u>Confidentiality</u>

How will subject confidentiality be protected?

Patients confidentiality will be protected using current OCOM patient privacy guidelines, which are fully HIPAA compliant. Patients receive a copy of the OCOM patient privacy guidelines to keep. If they have any questions, the practitioner is available to answer questions. Patient data will be entered electronically into an expanded clinical outcomes data base, consistent with current OCOM medical record keeping practices, as previously approved by the IRB.

Will *identifiable* subject data be transmitted to a person or office not associated with this institution?

NO

If yes, give name, address and title of person(s) receiving information.

Is HIPAA language included in Consent?

NO

(If no, explain) HIPAA language is already included in the current OCOM Patient Privacy Practices document, which all patients receive.

___ HIPAA waiver requested

5. Expenses

Will the subject incur expenses while participating in the study?

NO

If Yes, Who will pay for these expenses?

Will the subject receive payment in any form for participating in the study?

NO

If so, in what form and how will payments be determined?

6. Risks

Please list expected risks to subjects:

None are anticipated. The forms take approximately 15 minutes on average to complete.

Nature of risk

Seriousness Incidence/probability

What precautionary measures will be taken to eliminate or reduce risks:

NOT APPLICABLE

Will a Data Safety and Monitoring Board be needed?

NO

If yes, provide contact information.

7. <u>Benefits</u>

Please describe the benefits that can be expected from the proposed study for:

(a) Patient: **Improved long-term care, resulting from increased attention to clinical outcomes assessment and long term treatment planning, on the part of interns and supervisors.**

(b) Advancement of scientific/medical knowledge: **Improved ability to evaluate the clinical effectiveness of AOM treatment practices for a wide range of medical conditions seen in a large sample of OCOM clinic patients.**

8. <u>Assurances</u>

1. I agree to conduct this research study as reviewed and approved by the OCOM Institutional Review Board (IRB) and will promptly report to the Research Director or IRB Administrator any:

(a) proposed changes in the protocol,
(b) changes in the informed consent,
(c) unanticipated problems involving risk to subjects,
(d) serious adverse events to subjects
(e) change in any study personnel

2. I will not implement any changes to this research study, except where necessary to eliminate apparent immediate hazards to the subject(s), until approved by the OCOM IRB.

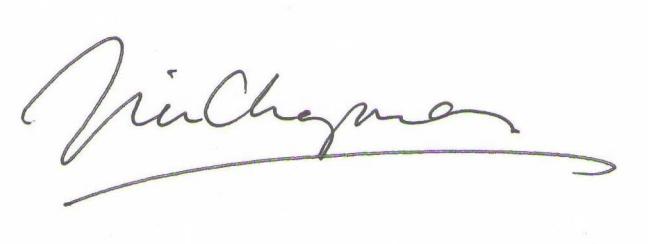
3. Since the Institutional Review Board is obligated to continually review this activity, I agree to furnish the Board relevant information on request and promptly report any significant new findings to the IRB and enrolled subjects.

4. I agree to accept responsibility for the ethical conduct of the project and the protection of the rights and welfare of the subjects.

5. I will retain the documentary evidence of informed consent for at least three years after the proposed activity has been completed or discontinued.

6. I agree to report any significant financial conflict of interest, i.e., anything of monetary value or in kind, including but not limited to salary or other payments for services (consulting fees or honoraria), equity interests (stock options or other ownership interests) and intellectual property rights that exceed $5,000 per annum.

7. I agree to report any financial benefits made available to me in connection with the conduct of this study that are in addition to the ordinary compensation for services.



_____ 8/13/09

Principal Investigator/Project Director [please PRINT and SIGN] Date

With this *completed* form, please include 2 copies of the following:

_____ Proposal
_____ Consent form
_____ Relevant publications
_____ Other supporting documents (recruitment tools, telephone screening dialogue, patient diaries, patient questionnaires)