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

Date _November 10, 2011__(Revised March 16, 2012)_____

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Proposal Title: _____OCOM Research Interest Follow-up Interviews_____

Funding Source: (list all that may apply)_NCCAM 3R25AT002879-04S1_____

Study type: ___ Prospective interventional (e.g., clinical trial) ___ Retrospective chart review

___ Secondary data analysis only _**X** Other (specify) __prospective qualitative study_____

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

Relevant research on acupuncture and Oriental medicine (AOM) is needed to contribute to the knowledge base on the treatment of a range of medial conditions. Such research requires the participation of practitioners to help design the studies, treat research subjects, and/or conduct outcomes-based studies in their own clinics. An important challenge for AOM has been the lack of research training for practitioners and research education opportunities for students at AOM colleges.

Our overarching goal is to design and implement research education initiatives and to provide opportunities for practitioners to participate in research. We propose to conduct in-depth interviews with a convenience sample of OCOM alumni, teaching assistants (TAs), and faculty who have indicated their willingness to be interviewed in a recently completed needs-assessment survey conducted by the OCOM Research Department, called the OCOM Research Interest Survey (ORIS). We surveyed our alumni, faculty and TAs to identify the extent of recent participation in acupuncture and Oriental medicine (AOM) research and interest in participating in future AOM research. *One hundred fifty members of the OCOM community completed the survey, representing a 15% response rate.*

The results of the ORIS showed us that a majority (>83%) of respondents had never received any training in research participation. Approximately 50% had participated in continuing education activities to enhance research literacy and in writing case studies, and nearly 40% had received training in evidence-based medicine and related statistical concepts, and had attended research conferences. More than half of the respondents indicated they would be interested in such research education opportunities as on-line courses; learning tips on how to discuss research with colleagues, patients, and the media; and learning basic study designs relevant to clinical practice.

We would like more detailed information about respondents' past research experience, interests in participating in future studies, and perceived needs for additional research education to help us plan future research education and participation initiatives. At the end of the ORIS, OCOM alumni, faculty and TAs had the option of entering their name and contact information if interested in being interviewed to obtain such detailed and specific information. *Forty three respondents (29%) indicated that they would be willing to be interviewed.*

The present IRB application will allow us to conduct these qualitative interviews *with the 43 respondents who provided their contact information. All 43 will be contacted and invited to participate. The format of these interviews will be 3-4 small focus groups of no more than 10 interviewees. If we can't obtain at least 10 participants, the project will be abandoned.*

All interviews will be conducted in the OCOM Research House. For respondents who live at a distance, we will conduct these interviews through a conference call. We will gather qualitative data regarding (i) the perceived role of research in the field of AOM), (ii) observations of individual attitudes about research and evidence informed practice, and (iii) feedback as to ways that OCOM might continue to provide research participation opportunities. In addition to developing research training opportunities for members of the OCOM community, we will summarize our findings in a research article that describes the research interests and experiences of AOM practitioners and teachers.

We anticipate that these focus group discussions will amplify and clarify data collected in the needs assessment survey.

2. **Sites/Subjects**

2a. Site(s) where research will be conducted: OCOM Research Dept.

2b. Estimated number of subjects from OCOM: *30-43*

Total number for project:____*30-43* (faculty, students, alumni)

2c. Characteristics of subjects: (check all that apply)

_X__Adults _____ Healthy Volunteers Sex: F_*X*__ M__X__

Age range___>21___

2d. Special Subject Categories (check as needed): NONE
Children _____ Subjects who may be incompetent _____ Prisoners _____

2e. If any of the above categories are checked, how will you assure they protected?
_____

2f. Source of Subjects: (clinic, general public, etc.) ___
This will be a convenience sample of prior survey respondents who indicated their willingness to be interviewed.

2g. Please describe how subject will receive Consent information:
Interested survey respondents will be emailed a recruitment invitation (attachment 1) informing them of the nature of the follow-up interviews along with a copy of the consent form (attachment 2) and instructions for accessing the Doodle calendar to indicate the times they are available to participate in the focus groups. Respondents who agree to be interviewed, will be asked to bring the signed consent form at the time of their scheduled interview.

3. Herbs/Devices
3a. Will Herbs be used? ___ Y _X_ N

3b. If yes, name of herb(s) and company:

3c. Form of the herbal formula: ____raw herbs ____ granules ____ patents

3d. Explain how the formula was determined & how herbs will be administered (capsules, tea, etc)

3e. Will a medical device be used? ___Y _X_N

3f. Is it an investigational device? ___Y _*X*_N

3g. Name of device and manufacturer: NA

4. <u>Confidentiality</u>

4a. How will subject confidentiality be protected?

Any information that is obtained in connection with this study and that can identify participants will remain confidential. Although the identities of interviewees will be known to the research team, no identifying information will be maintained in the audiotapes or subsequent transcripts. Audio recordings will be uploaded from the digital audio-recorder to the Research Department shared group drive, where access is password protected and limited to members of the research team.

4b. Will *identifiable* subject data be transmitted to a person or office who is not a member of the research team? ? ___Y _X_N

4c. If yes, give name, address and title of person(s) receiving information.

No identifiable information will be shared with anyone.

4d. What is information that will be shared with the above listed individuals?

The final paper summarizing the findings from interviews will be shared with interviewees at the time of publication.

4e. Is HIPAA language included in Consent? ___ Y _X N (if no, explain)

This is not applicable. No health information will be obtained from interviewees and no health information will be obtained from medical records.

4f. _X HIPAA waiver requested

5. <u>Expenses</u>

5a. Will the subject incur expenses while participating in the study? ___Y _<u>X</u>_N

For those interviews conducted by telephone, a toll-free conference call phone number will be used.

5b. Who will pay for these expenses? NA

5c. Will the subject receive payment in any form for participating in the study? ___Y _X_N

5d. If so, in what form and how will payments be determined? NA

6. <u>Risks</u>

6a. Please list expected risks to subjects:

The risk *from* participating in an interview on research experiences and interests will be minimal.

6b. Nature of risk

n/a

Seriousness Incidence/probability

6c. What precautionary measures will be taken to eliminate or reduce risks:

Interviewees will be instructed that they can decline to answer any question.

6d. Will a Data Safety and Monitoring Board be needed? ___Y _X_N

6e. If yes, provide contact information.

7. Benefits

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

(a) Patient:

n/a

(b) advancement of scientific/medical knowledge:

Clinically relevant research in acupuncture and Oriental medicine (AOM) requires the participation of practitioners, either by helping to develop the research protocols or by directly providing treatment in clinical trials. We intend to obtain information about the variety of research participation by practitioners and the types of research education they would like. We expect to offer such education in the future. By publishing our findings, we expect to encourage other AOM schools to provide research training and opportunities for participation to members of their faculty and alumni.

8. Assurances

8a. 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

8b. 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.

8c. 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.

8d. I agree to accept responsibility for the ethical conduct of the project and the protection of the rights and welfare of the subjects.

8e. I will retain the documentary evidence of informed consent for at least three years after the proposed activity has been completed or discontinued.

8f. 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.

8g. 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.

Deborah Ackerman 3/16/2012
Principal Investigator/Project Director [please PRINT and SIGN] Date

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

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