

**OREGON COLLEGE OF ORIENTAL MEDICINE
INSTITUTIONAL REVIEW BOARD
IRB Questionnaire (IRBQ)**

(To be submitted with the complete research proposal)

Date: 8-12-12

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

Nancy Grotton, Director of Student Affairs, ngrotton@ocom.edu

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Proposal Title: Mind-Body Medicine: An Experiential Course

Funding Source: (list all that may apply) OCOM Faculty Scholarship Grant

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

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

Dr. Coletto and Nancy Grotton recently introduced a course that teaches mind-body approaches – including meditation, guided imagery, biofeedback, breathing techniques, art, music, and movement – that can alleviate stress and foster self-awareness and self-care. Ten students enrolled and were asked to complete several questionnaires that measure stress/coping, mindfulness, and the students' perception of the role of mind-body medicine in enhancing self-awareness. The questionnaires were completed before the first class and after the last class, so that the instructors could evaluate the effectiveness of the course in enhancing coping, mindfulness, and perceptions of mind-body medicine. The

instructors are now seeking IRB approval to share their findings from this first course with other educators.

The purpose of the course is to introduce a variety of mind-body self-awareness and stress-reduction modalities to the student for self-care use and to gain insights into clinical use with patients. This course is offered to a maximum of 10 first year OCOM students. During the winter quarter, the group meets for two consecutive hours on Tuesday evening beginning on January 3 for 11 weeks with Joe and Nancy, who will facilitate the sessions. Participants engage in various techniques; are given the opportunity to discuss them with members of their small group; and are encouraged to practice daily the skills taught in order to incorporate these learned skills into daily life.

Each weekly session begins with a short meditation. This is followed by a check-in period where each participant discusses the life events and feelings of the past week along with any insights gained by practicing new mindfulness techniques learned during the previous week's session. Participants may decline to speak during this time. After the check-in period, a new mindfulness technique is presented and practiced. This is followed by a discussion of how that technique felt to each participant. Again, participants may decline to speak. The session is brought to a close by another short meditation. Additional recommended readings and resource material are presented.

At the onset of the first session, participants complete three surveys regarding stress and mindfulness; the Perceived Stress Scale, the Mindful Attention Awareness Scale, and a Mind-Body Medicine questionnaire. At the conclusion of the final session, participants complete the same three surveys plus one open-ended, qualitative questionnaire regarding their experience in the course and its effect on their daily lives. Scores on these questionnaires are helping us to evaluate the effectiveness of this course in helping individual students cope with stress.

This application is for a secondary analysis of these data so that we can share our experience in this course with other educators. We will enter all of the questionnaire data into a database for statistical analyses. We will compare before and after scores using the paired T-Test, calculate change scores on stress and mindfulness, and evaluate the potential correlation between change in mindfulness and change in coping. Qualitative data obtained from the open-ended questionnaire will be coded and recurring themes will be identified using

3g. Name of device and manufacturer:

4. Confidentiality

4a. How will subject confidentiality be protected?

The last four digits of each participant's phone number was used on the pre and post survey forms so that we could compare responses before and after the course. No other identification was used; we do not access the complete phone numbers. Only members of the research team have access to the completed forms and to the database.

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

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

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

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

There is no clinical information involved in this project.

4f. HIPAA waiver requested

5. Expenses

5a. Will the subject incur expenses while participating in the study?
 Y N

5b. Who will pay for these expenses?

5c. Will the subject receive payment in any form for participating in the study? Y N

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

6. Risks

6a. Please list expected risks to subjects:

This is a secondary analysis of data collected to evaluate individual students' response to a mind-body course. All data are anonymous. No identifying information is obtained on the questionnaires.

6b. Nature of risk

Seriousness minimal

Incidence/probability minimal

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

The last 4 numbers of the students' phone numbers have been used on each form. No other identifying information is captured. The data are maintained in a secure office on the OCOM campus that only members of the research team can access. The raw data will be entered into a computer database for analysis, and that database is password protected so that only members of the research team can access it.

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: (Student) The individual students who participated in the course will not directly benefit from this proposed analysis. We anticipate the following benefits of this training to individual students will be observed.

Stress reduction

Increased self awareness

Learning mindfulness techniques for self care

Improved focus

Improved learning

Increased level of health and well being

Better communication with classmates and others

Learning mindfulness techniques for clinical use with patients

(b) advancement of scientific/medical knowledge:

Information on the effectiveness of mind-body awareness obtained from this first course will be shared with other educators, adding to the data regarding the use of a mind body course in a medical school program to help students:

Decrease stress and burn out

Improve learning

Live more fulfilling lives

Communicate more effectively

Be more effective in helping patients in a variety of clinical settings

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.

Joseph J. Coletto, N.D., L.Ac.

Joseph J. Coletto, N.D., L.Ac.

9-5-12

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)