OREGON COLLEGE *of* ORIENTAL MEDICINE

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Institutional Review Board Questionnaire (IRBQ)

(To be submitted with the complete research proposal)

Date _____

Principal Investigator _____

Phone _____ Affiliation with OCOM _____

Email address _____

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

Proposal Title:

Funding Source (List all that may apply):

Study type (Check one):

- ☐ Systemic Review
- ☐ Experimental/Interventional Study (e.g., RCT)
- ☐ Prospective Observational Study (e.g. cohort)
- ☐ Retrospective Observational Study (e.g. cohort, cross-sectional, case control)
- ☐ Survey
- ☐ Retrospective Chart Review
- ☐ Secondary Data Analysis Only
- ☐ Other (Specify):

1. Abstract of Proposal

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

2. Sites/Subjects

2a. Site(s) where research will be conducted

2b. Estimated number of subjects from OCOM ☐ Total number for project ☐

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

☐ Adults ☐ Healthy Volunteer Sex: ☐ Female ☐ Male Age range: ☐

2d. Special Subject Categories (Check all that apply):

☐ Children ☐ Prisoners ☐ Subjects who may be incompetent

☐ Other (Specify) ☐

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

2f. Source of Subjects (clinic, general public, etc.):

2g. Describe how subject will receive consent information:

3. Herbs/Devices

3a. Will herbs be used? ☐ Ycq ☐ Nm

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

3c. Form of the herb/herbal formula (Select all that apply): ☐ Raw ☐ Granules ☐ Patents ☐ Other

3d. Explain how herbs will be administered (capsules, tea, etc.):

3e. Explain how the formula was determined:

3f. Will a medical device be used? ☐ Ycq ☐ Nm

3g. Is it an investigational device? ☐ Wcq ☐ Lm

3h. Name of device and manufacturer:

4. Confidentiality

4a. How will subject confidentiality be protected?

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

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? ☐ Wcq ☐ Lm (if no, explain)

4f. HIPAA waiver requested? ☐ Wcq ☐ Lm (if no, explain)

5. Expenses

5a. Will the subject incur expenses while participating in the study? ☐ Wcq ☐ Lm

5b. Who will pay for these expenses?

5c. Will the subject receive payment in any form for participating in the study? ☐ Wcq ☐ Lm

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

6. Risks

6a. Please list expected risks to subjects:

6b. Nature of risk:

Seriousness:

Incidence/probability:

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

6d. Will a Data Safety and Monitoring Board be needed? ☐ Ycq ☐ Nm

6e. If yes, provide contact information:

7. Benefits

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

(a) Patient:

(b) The advancement of scientific/medical knowledge:

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 IRB 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.

Please PRINT and SIGN:

Principal Investigator/Project Director

Signature

Date

With this *completed* form, please submit a copy of the following:

- ☐ Dull Study Proposal
- ☐ Amnsent For k
- ☐ Pelevant Publications
- ☐ Other supporting documents (recruitment tools, telephone screening dialogue, n_rgc l r bg_pgcq* patient questionnaires)