



OREGON COLLEGE *of* ORIENTAL MEDICINE

INSTITUTIONAL REVIEW BOARD

POLICIES AND PROCEDURES

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I. INTRODUCTION

This document is designed to serve as a guide to the regulations and responsibilities of the Institutional Review Board (IRB) of the Oregon College of Oriental Medicine (OCOM). The first responsibility of IRB members is to familiarize themselves with these policies.

II. INSTITUTIONAL REVIEW BOARD

A. What is an IRB?

According to regulations set by the U.S. Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA), an IRB is a formally designated group that is established at an institution engaged in research involving human subjects. Specifically, the IRB insures compliance with DHHS Code of Federal Regulations, Title 45, Part 46 (See Appendix A).

While IRB approval is legally required only for federally funded research projects, OCOM Research Department policy requires all OCOM-related research involving human subjects to be reviewed and approved by its IRB. This and other policies established by the OCOM Research Department have been approved by the OCOM Executive Council.

The IRB is primarily concerned with safeguarding the rights and well being of human subjects, focusing particular attention on the ethical implications of the proposed research procedures. OCOM has agreed to adhere to the Ethical Principles for the Protection of Human Subjects of Research of the DHHS Belmont Report (See Appendix B). All Investigators have a responsibility to conduct research activities in a manner that provides maximum protection for the rights and welfare of the community they serve. OCOM is committed to conducting all of its research activities under the most rigorous ethical standards.

The IRB is not charged with determining the basic scientific merit and value to medical and health research of the proposed research study. Scientific review of the proposed protocol, utilizing peer review and expert consultation, should occur prior to submission of the protocol to the IRB. Should the IRB feel that such a review has not occurred, or was done in a superficial manner; the application will be returned to the Investigator.

Questions regarding interpretation of regulations governing research activities should be directed to the OCOM Dean of Research or to the DHHS Office for Human Research Protection (OHRP), whose address is listed in Appendix C.

B. How is IRB membership determined?

Membership of the IRB is determined by the OCOM Dean of Research and consists of at least five voting members. At least one member must not otherwise be affiliated with OCOM, and one member must belong to a non-scientific profession. IRB members should be knowledgeable of IRB regulations and responsibilities, as well as standards of professional conduct. The IRB will consist of individuals who represent diverse backgrounds, are sensitive to community attitudes and knowledgeable and experienced with vulnerable subjects. Additional non-voting members who have particular expertise may be appointed from time to time on an as-needed basis, serving as ad hoc consultants.

Selected from the voting members will be an IRB Chair whose main duties involve assigning primary and secondary reviewers for research protocols, running the meetings, reviewing expedited and exempt study submissions outside of full IRB meetings and coordinating with the IRB Administrator (see below) to ensure that notification of IRB decisions occurs in a timely manner.

An additional non-voting member is the IRB Administrator, who will set meeting dates, distribute research proposals to IRB members prior to meetings, record and maintain minutes of all IRB meetings and generally serve to facilitate the functioning of the IRB.

Formally appointed alternate members may be used when primary members are unable to attend a meeting. Alternates will have similar qualifications to the members they are substituting for. The IRB is required to have an alternate for the non-scientific member. The meeting minutes will list the alternate and the member they are replacing.

C. What is the scope of IRB responsibility?

All IRB members must complete and maintain federally-mandated ethics training.

The IRB has as its primary responsibility the review of all research activities involving human subjects to assure that:

1. The risks to the research subjects are outweighed by the possible benefit to the subjects and/or the importance of the knowledge to be gained (risk vs. benefit ratio);
2. The rights and welfare of each subject are adequately protected;
3. Informed Consent contains all elements required by federal regulations;
4. Studies are reviewed at specified intervals; and
5. Expedited, Exempt and select Continuing Review submissions can be reviewed outside of full meetings by the IRB Chair or a designated member of the IRB. These submissions will be reviewed in a timely manner with the reviewers submitting their decision within two weeks of receiving the study from the IRB Administrator.

The IRB is authorized to:

- (a) Approve, disapprove, or request modification of research protocols;
- (b) Conduct continuing review of studies and approve changes in protocols; and
- (c) Suspend or terminate approval of IRB-approved research.

III. PROCEDURES GOVERNING IRB ACTIVITIES

A. Meetings

The IRB will meet on an as-needed basis to review submitted proposals. The IRB Administrator will notify IRB members approximately three weeks prior to scheduling an IRB meeting time. Materials for review will be sent to IRB members at least one week prior to the meeting date. Once an IRB meeting has been scheduled, only proposals that have been submitted to the IRB Administrator a minimum of 14 calendar days before the date of the meeting will be reviewed at that meeting.

Guidelines for the IRB meeting Order of Events are available (see Appendix A). Inclusion of the Investigator at the IRB meeting will be decided on an individual basis and may occur if it is determined that such inclusion will benefit the review process. The Investigator may be invited to offer information and answer questions but will not be present during the voting process.

IRB Meetings: Order of Events

1. Call to Order by Chair.
2. Review, edit and vote to accept/reject minutes from previous meeting.
3. Review study(s):
 - a. Primary reviewer presents overview of study and Consent Form;
 - b. Secondary reviewer adds additional comments;
 - c. Group discussion on risk/benefit ratio and revisions of Consent Form;
 - d. Chair presents overview of issues, asks for motion; and
 - e. Members introduce motion (approval, conditional approval, deferral, disapproval), second motion, vote.
4. Additional items or issues are discussed:
 - a. Annual reviews, expedited reviews, serious adverse events, other information requested by IRB from PI on particular studies.
5. Chair asks if there is other business:
 - a. If there is other business to discuss, chair determines best course of action (e.g., assign committee, hold till next meeting, etc.).
6. Chair closes the meeting if no other business.
7. Meeting Adjourned.

B. Submission of a Research Protocol

Any research that involves any OCOM faculty member, alumnus, student, or staff member acting on OCOM's behalf shall be reviewed by the OCOM IRB.

Only faculty, students, staff or alumni of OCOM may submit proposals to the OCOM IRB for review and must be either the Investigator or Co-Investigator on the proposal. All investigators, practitioners and study staff must complete research-related ethics training prior to participating in a research study and provide documentation of completion of that training.

Submission process for research protocols:

The first step an Investigator must take is to complete the Institutional Review Board Questionnaire (IRBQ, Appendix F) and submit it to Mike Law, IRB Administrator. The IRBQ requires a brief description of the proposed research including the hypothesis, aims, funding source, prior scientific review and risk/benefit considerations, along with supporting materials including the full research proposal and (as appropriate) consent forms, recruitment materials, surveys/questionnaires, etc.

Studies that have not been subject to a scientific review will be sent to the OCOM College Research Committee (CRC) for a scientific review. The IRB Administrator will send the required materials to the CRC and act as a liaison between the IRB and the CRC.

IRB Questionnaire (Appendix F). This form alerts IRB members to key aspects of the aims and procedures of the proposed research, particularly as they apply to the recruitment, experimental use and safeguards of human subjects. (The IRBQ is available from the IRB Administrator or can be downloaded from the Research Department web site, http://research.ocom.edu/index.php?option=com_content&view=article&id=144&Itemid=159.)

Once submitted, the IRBQ and proposal will receive a number from the IRB administrator. That number will be used as reference and will be displayed on all documents concerning the study.

When collaborative research projects exist with other institutions or organizations, the IRB may:

- Review and approve those research activities even when the collaborating institution has already conducted its own human subjects review in accordance with current federal regulations, or
- Defer IRB oversight to another IRB that has a current FWA once the appropriate documentation is in place.

All Research Proposals must include an IRB Questionnaire.

C. Review Process

A review must occur at a convened meeting where a quorum is present. To qualify as a quorum, one non-scientific and at least one scientific member must be present. To approve research, the IRB must determine that all of the requirements specified in CFR Title 45 Part 46.111 (see Appendix B) are satisfied. In brief, these requirements are:

- (1) Risks to subjects are minimized.
- (2) Risks to subjects are reasonable in relation to anticipated benefits.
- (3) Selection of subjects is equitable. (The IRB has the right to require that minorities and non-English speaking people are included in the study.)
- (4) Informed consent will be sought.
- (5) Informed consent will be documented.
- (6) Data monitoring procedures are in place.
- (7) Means for privacy/confidentiality of data are adequate.
- (8) Safeguards are in place to protect against coercion or undue influence of subjects. (This includes an assessment of whether compensation, if any, is appropriate.)
- (9) HIPAA standards for safeguarding Protected Health Information (PHI) are being met.

For each study, there will be a primary and a secondary reviewer. The primary reviewer will be chosen based primarily on the area of expertise relative to the study subject matter. The secondary reviewer will be chosen with a differing perspective, if possible. The primary and secondary reviewers will receive full protocol packets. The rest of

the board will receive the IRBQ, proposal, consent form, and any accompanying documents. Each reviewer will complete and sign a form documenting their review criteria, which will be kept by the IRB Administrator. In order for the research to be approved, the study must receive approval of a *majority* of the members present at the meeting. IRB members who have a conflict of interest in a proposal under review may be consulted to answer any questions raised but they must be absent from the room during the discussion and voting process. The IRB must notify Investigators in writing of its decision to approve, modify, or disapprove their research proposal (see below).

D. Categories of Action

The IRB has the following decision options:

1. Approval

The protocol is approved as submitted.

2. Conditional Approval

The problems identified in the protocol are not serious and typically fall into two categories: (1) minor changes need to be made in the informed consent document, or (2) the Investigator needs to clarify an aspect of the study or provide additional information. In such instances, the IRB Chair can give expedited approval, after the Investigator submits a written response to the IRB's questions and concerns. *Subjects cannot be recruited until written approval is received.*

3. Deferral

The changes proposed or questions raised by the IRB are significant enough to warrant review of the proposal again at a subsequent meeting after the Investigator has submitted additional information. Typically, this may occur in instances where the IRB did not have enough information to make a risk/benefit determination.

4. Disapproval

The research places the subjects at risks that significantly outweigh the benefit or value of the knowledge to be gained, or it raises ethical issues that are deemed unacceptable. If disapproval is anticipated, the Investigator may be asked to attend the IRB meeting to discuss the protocol. *In case of disapproval, the only recourse available to an Investigator is to revise and resubmit the proposal to the IRB.*

E. Other Types of Review

1. Exempt

Federal Regulations 45 CFR 46.101 (b) provides a definition of research that may be exempt from the regulations (Appendix D). Examples of "Exempt" research include surveys or studies using information in which subjects cannot be identified. Observations of public behavior, quality assurance reviews or clinic patient satisfaction surveys where there is no direct contact between patients and surveyors.

However, please note that research involving patient chart reviews and/or review of subject data through a computer database/medical record/employee record *where identifying information (name, medical record number, employee identification number, social security number) is recorded or maintained* must be approved by the IRB. This requirement applies to record reviews and database queries performed for the purposes of testing a hypothesis and drawing conclusions that will contribute to knowledge that can be generalized.

Additionally, any project that requires verbal contact with OCOM patients to gain research-related information will need IRB approval.

2. Expedited

Expedited review is a procedure through which certain kinds of research authorized by 45 CFR 46.110 and 21 CFR 56.110 may be reviewed and approved without convening a meeting of the entire IRB. There are several [types of research that may qualify for Expedited review](#).

In general, research may be considered for Expedited review if it involves no more than minimal risk, does not include intentional deception, does not employ sensitive populations or topics, and includes appropriate

consent procedures. Expedited review may also be used when minor changes have been made to a previously approved research project during the period (of one year or less) for which approval is authorized.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those encountered in daily life or during the performance of routine physical or psychological examinations or tests. Please keep in mind that research does not count as having "minimal risk" simply because it involves minimal physical risk or is non-invasive. There are many kinds of risk including financial risk, employment risk, criminal/civil liability, stigmatization, insurability and embarrassment. It is important to consider all of these when assessing risk.

3. Continuing

Except for studies determined to be exempt from IRB oversight, all human subject's studies are required to undergo continuing review based on the level of risk as assessed by the IRB. This review takes place no less than annually, and may require more frequent review or reports as determined by the IRB. For projects receiving full board review, the length of approval is calculated from the date of the full board review. When a primary reviewer has been assigned, that reviewer is asked to provide a recommendation for the length of approval. The appropriate length of approval is considered as a part of the full board discussion. That review may take place up to thirty (30) days prior to expiration.

Continuing review of expedited or full board approved research will be conducted with the same diligence as utilized with the initial review of the research. The review should be substantial and complete. Reviewers have access to the original submission, all documents submitted since the beginning of the research and any new documentation submitted with the continuing review application.

For projects approved via the expedited process, the chair, vice chair or experienced member designee conducts the review and determines the length of approval but, the approval time is still no greater than annual.

For research where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions, continuing IRB review is required as long as the research remains active only for long-term follow-up of subjects. Furthermore, continuing IRB review of research is required where the remaining research activities are limited to data analysis (see 63 FR 60364-60367, category (8)).

F. Additional Areas of IRB Concern

1. Changes in Approved Protocols

Should an Investigator desire to change any aspect of a protocol subsequent to IRB approval, such proposed change(s) must be submitted, with rationale for the change, for IRB review on a Protocol Revision and Amendment Form (PRAF) (see Appendix G). Under certain conditions, these types of changes may be expedited. *Any change in a study protocol must have IRB approval prior to implementation of the change, except when necessary to eliminate apparent immediate hazards to the subject.*

2. Adverse Event Reports/Subject Complaint

Federal regulations (FDA & NIH) specify that investigators "promptly report...all unanticipated problems involving risk to human subjects" (21CFR312.66). The means and format of reporting is not indicated. This policy is written to provide OCOM investigators guidance in the reporting of Serious Adverse Events.

DEFINITIONS

Adverse Event	Any untoward medical occurrence in a patient or clinical investigation subject administered an investigational product which does not necessarily have a casual relationship with this treatment. An adverse event can be therefore any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of an investigational product. Adverse events are routinely reported to sponsors but not to the IRB.
Serious Adverse Event (SAE)	Any experience that suggests a significant hazard, contraindication, side effect or precaution and any experience that is fatal or life threatening, is permanently disabling, requires in-patient hospitalization or is a congenital anomaly, cancer or overdose, whether or not it is related to investigational drug or device therapy.
On-Site SAE	A Serious Adverse Event reported concerning a research subject enrolled in a clinical trial whose Principal Investigator is conducting that study either in their clinic in Portland or at an OCOM facility or in collaboration with OCOM.
DSMB	Data Safety and Monitoring Board is an organization that is responsible for analyzing adverse events in multi-site studies.

3. Maintenance of Confidentiality

If, for any reason, identifying information has to be released to entities not mentioned in the Consent Form, the IRB must first be notified. HIPAA standards regarding Protected Health Information (PHI) must be followed. (See # 8 below regarding HIPAA requirements)

4. Suspension or Termination of Research

The IRB may suspend or terminate any research associated with unanticipated problems involving risks to subjects or others, or research that is not being conducted in accordance with the IRB's policies, recommendations, or restrictions. The IRB will notify the appropriate agencies if any suspension or termination has occurred due to non-compliance or unanticipated problems.

5. Study Closure

The investigator must report all changes in study status, *including completion of the study*, to the IRB. A final report notice allows the IRB to close its files and provides information that it may use in the evaluation and approval of other studies.

6. Study-Related Procedures Performed Prior to Obtaining Signed Consent.

In the event of a study related procedure being done before the Consent Form is signed, the Investigator must notify the IRB of the circumstances surrounding the event.

7. Federal-wide Assurances (FWA).

OCOM is responsible for ensuring that independent investigators engaged in research activities involving OCOM patients, clients or students will operate under FWA guidelines and will complete a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. Collaborating institutions that do not have their own FWA may operate under the OCOM FWA with the approval of the supporting Department or Agency, if appropriate. OCOM or another FWA-approved IRB may defer to one or the other on collaborating research projects with appropriate documentation and registration at the FWA site.

8. Reporting

The IRB shall send periodic reports to the OCOM Executive Council (EC), in the form of meeting minutes following IRB meetings. The IRB shall also report to the EC any non-compliance issues or unanticipated problems involving risks to subjects or others that lead to suspension or termination of a study.

9. Study Auditing

The IRB may determine when a study shall be audited to determine compliance. Audits will be conducted randomly, when there seems to be a problem with the study conduct or based upon study complexity.

Inexperienced PIs or PIs who have been non-compliant in the past will be considered for audit. A neutral party will conduct the audits.

10. *HIPAA Oversight*

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 Code of Federal Regulations Parts 160 and 164) covers any use or disclosure of protected health information (PHI) by a covered entity, including the conduct of research, recruitment into research projects and review of medical records for research purposes.

This IRB is committed to following these standards. Each IRB member will receive the training book, "HIPAA Training Handbook for Researchers: HIPAA and Clinical Trials" by Lawrence H. Muhlbaier, Ph.D. as a reference. Most questions regarding HIPAA regulations in the setting of clinical research can be answered by using this manual, but the IRB Administrator and the Dean of Research are available to answer any questions regarding the maintenance of confidentiality and HIPAA.

In order to create an environment in which HIPAA standards may be upheld, the IRB is required to do the following:

1. Designate a privacy officer who will be responsible for implementing privacy policies and ensuring that they are followed;
2. Designate a contact person for complaints. This person will be available as a contact if a patient feels that the security of their PHI has been compromised;
3. Receive training in HIPAA regulations; and
4. Create a policy for addressing confidentiality compromises. This includes sanctions against those who have knowingly violated HIPAA requirements.

Research institutions must obtain permission from a patient to use or disclose their PHI for research purposes. When the IRB reviews a research study, it must determine which of the following procedures must be followed by the Principal Investigator to be compliant with HIPAA regulations:

1) Include a *HIPAA Authorization form* (Appendix H) with the informed consent for the study. In most studies involving human subjects, an authorization will be required. An authorization is *not* required if the research qualifies for a waiver of authorization (as explained under #2 below), the IRB has approved a review preparatory to research (#3 below) or research is being conducted on PHI from decedents.

The authorization form will be given to the PI by the IRB administrator and **MUST** be signed by all patients who sign a consent form for participation in the study. This form must be kept for at least 6 years after the patient has signed it. According to the HIPAA regulations, this form must include the following:

- A. *The Protected Health Information you plan to use or disclose;*
- B. *Identification of persons who may use or disclose the PHI;*
- C. *Identification of persons who may receive the PHI;*
- D. *A description of each purpose of the use or disclosure*
- E. *Expiration date or event, after which you will cease to use or disclose the PHI;*
- F. *An explanation that the patient may refuse to sign the authorization;*
- G. *An explanation that the patient may revoke authorization of use/disclosure of PHI, but must do so in writing;*
- H. *A statement regarding the possibility of re-disclosure by a party receiving this PHI, and a statement referring to the PI's attempt to prevent this from occurring; and*
- I. *Participant's signature and date.*

11. *Research Integrity - Guiding Principles*

OCOM requires integrity and competence in the conduct of research. The goals of the OCOM research program are to increase scientific knowledge, improve the quality of patient care, and enhance scholarship within OCOM and the profession of acupuncture and Oriental medicine. To these ends, all research must be conducted according to the highest standards of scientific design and must be guided by ethical principles that ensure protection of the rights of human subjects, avoid causing harm, and aim to benefit individuals, communities, and society-at-large.

Research Integrity Policy – Guiding Principles

1. Seeking and imparting knowledge are fundamental to OCOM’s academic mission. It follows that researchers have the obligation to perform ethical and high quality research and to communicate results to the profession and to the public.

2. All research must adhere to sound principles of scientific design and be conducted in a manner that will ensure the accuracy of data and permit valid conclusions. Research studies should examine specific questions or test specific hypotheses in study designs that have a high probability of reaching definitive conclusions.

3. The rights and safety of research subjects are of paramount importance.

4. Topics of research must be consistent with the interests of OCOM, collaborating institutions, the health professions, and society-at-large.

5. OCOM students should be taught the principles of ethical and methodologically sound research and should be carefully supervised by faculty mentors in the conduct of research.

6. Research studies must be managed efficiently so that maximal value is obtained from the expenditure of public or private funds.

7. Additional information on the ethical conduct of research can be found in the Belmont Report and in the U. S. Department of Health and Human Services (HHS) regulations for Protection of Human Research Subjects (45 CFR 46, as amended), Protecting Human Research Participants.

<http://www.hhs.gov/ohrp/archive/documents/19790418.pdf> and

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Related Policies and Publication

The IRB policy is to be read and considered in conjunction with other related College policies, including but not limited to:

1. Intellectual Property, Conflict of Interest, and Conflict of Commitment Policy;
2. Information Technology Use Policy;
3. OCOM Copyright Fair Use Policy;
4. Grant Funding and Administration Policies;
5. Research Integrity Policy and Research Misconduct Procedures; and
6. Other applicable OCOM policies.

The IRB Policy shall be published and included in OCOM College publications and documents as needed to ensure that all College communities of interest are advised of the contents of this Policy. These publications include, but are not limited to:

1. the OCOM Faculty Handbook,
2. OCOM Masters and Doctoral Program Student Handbooks,
3. OCOM Staff Employment Policies,
4. OCOM College Catalog, and
5. other College publications as needed.

Policy on Intellectual Property

As a graduate institution of higher education, OCOM values and supports Academic Freedom, the free exchange of ideas and opinions. Changes in information technology and copyright law require clarification of the rights and responsibilities that accrue from the creation of works of authorship (hereinafter “works”) at the College so that individuals can create, use, and disseminate intellectual property to fulfill their respective functions in and outside the College. Copyright includes a bundle of rights—including rights to ownership, reproduction or copying, preparation of derivative works, distribution, **public display, and public performance. General principles regarding this bundle of rights in works created at the College are set forth in OCOM’s policy regarding Intellectual Property. In particular instances, written agreements may be necessary to modify the rights outlined below, or to clarify the rights and responsibilities of interested parties to a greater level of specificity.**

OCOM’s policy on Intellectual Policy applies to works produced by College faculty, staff, students, other members of the College community, and contractors. This policy generally provides that faculty members and students own the copyrights to works they produce during their academic careers at OCOM, subject to limited contractual exceptions, and in certain circumstances, limited use rights.

Policy on Conflict of Interest and Conflict of Commitment

OCOM is committed to basic values of transparency, integrity of scholarship, and independence as it pursues its mission to transform health care by educating highly skilled and compassionate practitioners, providing exemplary patient care, and engaging in innovative research within a community of service and healing. Accordingly, the College allows and encourages faculty and staff to engage in outside activities and relationships that enhance the mission of the College. All faculty and staff members are to act with honesty, integrity, and in the best interest of the College when performing their duties, and to abide by the highest standards of research, educational, professional, and fiscal conduct.

Given that the College allows and encourages outside activities and relationships that enhance the mission of the College, potential conflicts of interest and commitment are inevitable. Outside activities should not, however, interfere with an individual’s College obligations. Faculty and staff must not use their official College positions or influence to further gain or advancement for themselves, parents, siblings, spouse or partner, children, dependent relatives, or other personal associates, at the expense of the College. Full-time members and staff members with 50% or more appointments owe their primary professional commitment to the College. Accordingly, a commensurate commitment of time and intellectual energy should be used to support and enhance the mission of the College. Other part-time faculty members and staff members owe time and effort commitments to the College commensurate with their appointments.

All actual and potential conflicts of interest or commitment must be disclosed to a designated College official, evaluated, and, if found to be significant, eliminated or managed as described in Conflicts of Interest and Conflicts of Commitment Policy. This policy is consistent with and in addition to relevant federal and state law and College policies and with other relevant College policies. Academic or administrative units may require further disclosure and conflict management than mandated by this policy as may be deemed appropriate by the unit and its supervising administrator. This policy is meant to be a supplement to good judgment, and all trustees, employees and volunteers must respect its spirit as well as its wording. In order to serve as a trustee, employee or volunteer, it is a requirement to read these policies and agree to abide by their terms.

Ownership and Retention of Research Records

In keeping with governmental guidelines, OCOM requires that research records be retained for a minimum of five years after completion and publication of the study. Both the principal investigator and OCOM have responsibilities and, therefore, rights concerning access to, use of, and maintenance of original research data. The principal investigator has primary responsibility for recording, retaining, and storing research data. However, the data also belong to the institution in which the research was conducted. The institution can be held accountable for the integrity of the data even after the researchers have left the Institution.

G. IRB Records Maintenance

The OCOM IRB will maintain records of all of its activities, including the following:

1. A current list and résumés or CVs of IRB members;
2. Confirmation of ethics training by IRB members and investigators and practitioners;
3. Written procedures describing the scope of IRB activities and responsibilities;
4. Copies of all human subject proposals, approved consent forms, progress reports by Investigators, and adverse reaction reports and subject complaints;
5. Minutes of IRB and any other meetings relevant to a given protocol. These minutes should include enough detail to indicate attendance, voting actions, protocol approvals, conditional approvals, deferrals, disapprovals, and the basis for any changes requested. The IRB will also keep detailed records of any controversial discussions and/or decisions. If a member in attendance has a conflict of interest regarding any project, the minutes should show that this member did not participate in the review, except to provide information requested by the IRB;
6. Records of continuing review activities; and
7. Copies of all correspondence between the IRB and each Investigator.

IRB records must be maintained for at least five years after the end of a study. Records are accessible for inspection and copying as required by government regulations.

APPENDIX A

*Department of Health and Human Services
Code of Federal Regulations
Title 45, Part 46
Protection of Human Subjects*

Human Subjects in Research

http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr46_99.html

This site will access the current Code of Federal Regulations

APPENDIX B

The Belmont Report

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

II. The Belmont Report (a summary)

Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect for persons, beneficence, and justice.

A. Respect for Persons incorporates at least two ethical convictions:

1. *Individuals should be treated as autonomous agents.*

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others.

2. *Persons with diminished autonomy are entitled to protection.*

The capacity for self-determination matures during the life of an individual and may be lost, wholly or in part, because of illness, mental disability, or circumstances that severely restrict liberty. Some persons are in need of extensive protection; for others, it is only necessary to ensure that they undertake activities freely and with awareness of possible adverse consequences. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit.

B. Beneficence, in this Report, is understood as an obligation and incorporates these rules:

1. *Do not harm.*

However, even avoiding harm requires learning what is harmful which may expose individuals to risk as may the process of learning what will benefit. The problem is to decide when it is justifiable to seek certain benefits despite the risks involved.

2. *Maximize possible benefits and minimize possible harms.*

C. Justice

1. *The burdens and benefits of research should be justly distributed.*

The selection of research subjects needs to be scrutinized to determine whether some classes are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.

APPENDIX C

Office for Human Research Protection (OHRP)

The IRB Administrator and the Dean of Research have copies of the OHRP publication, “Protecting Human Research Subjects: Institutional Review Board Guidebook”. This guidebook was designed as a reference book to assist IRB members, Investigators, and the Dean of Research in fulfilling their responsibilities for protecting the rights and welfare of human subjects. The Guidebook is in loose-leaf format, and contains regulations, relevant institutional documents, text dealing with specific topics, a glossary of terms, and a bibliography of sources. It contains the following chapters:

- Introduction (Background and purpose of the IRB review system);
- The Belmont Report principles;
- Institutional Administration;
- Regulations and Policies;
- Basic IRB Review;
- Consideration of Research Design;
- Biomedical and Behavioral Research; and
- Special Classes of Subjects.

The Division of Human Subject Protections of OHRP is available to answer questions about the protection of human subjects and compliance with federal regulations and OHRP guidelines. OHRP can be contacted at:

Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852
Toll-Free Telephone within the U.S. (866) 447-4777
Telephone: (240) 453-6900
Fax: (240) 453-6909
e-mail: ohrp@osophs.dhhs.gov
Website: <http://www.hhs.gov/ohrp/>

APPENDIX D
RESEARCH CAN BE EXEMPT FROM IRB REVIEW IF IT COMPLIES WITH THE FOLLOWING:

45 CFR 46 101(b) states:

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
 - (i) research on regular and special education instructional strategies, or
 - (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
 - (i) the human subjects are elected or appointed public officials or candidates for public office; or
 - (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - (i) Public benefit or service programs;
 - (ii) procedures for obtaining benefits or services under those programs;
 - (iii) possible changes in or alternatives to those programs or procedures; or
 - (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies,
 - (i) if wholesome foods without additives are consumed or
 - (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.¹

¹ Institutions with HHS-approved assurances on file will abide by provisions of Title 45 CFR part 46 subparts [A-D](#). Some of the other departments and agencies have incorporated all provisions of Title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at [45 CFR 46.101\(b\)](#) do not apply to research involving prisoners, [subpart C](#). The exemption at [45 CFR 46.101\(b\)\(2\)](#), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, [subpart D](#), except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

APPENDIX E

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure¹

Applicability

- A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- B. The categories in this list apply regardless of the age of subjects, except as noted.
- C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- D. The expedited review procedure may not be used for classified research involving human subjects.
- E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
- F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

- 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- 3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
 - a. hair and nail clippings in a nondisfiguring manner;
 - b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
 - c. permanent teeth if routine patient care indicates a need for extraction;
 - d. excreta and external secretions (including sweat);
 - e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
 - f. placenta removed at delivery;
 - g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

- h. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
 - i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
 - j. sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
 6. Collection of data from voice, video, digital, or image recordings made for research purposes.
 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
 8. Continuing review of research previously approved by the convened IRB as follows:
 - a. Where
 - (i) the research is permanently closed to the enrollment of new subjects;
 - (ii) all subjects have completed all research-related interventions; and
 - (iii) the research remains active only for long-term follow-up of subjects; or
 - b. Where no subjects have been enrolled and no additional risks have been identified; or
 - c. Where the remaining research activities are limited to data analysis.
 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

¹ An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](#).

² Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR 46.402\(a\)](#).

More information can be obtained at: <http://www.hhs.gov/ohrp/policy/expedited98.html>

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

(To be submitted with the complete research proposal)

Date: _____

Principal Investigator: _____

Phone: _____ **Affiliation w/OCOM:** _____

Email address: _____

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

Proposal Title: _____

Funding Source: (list all that may apply) _____

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

___ Retrospective Cohort Study ___ 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 Volunteers Sex: F____ M_____

Age range _____

2d. Special Subject Categories (check as needed):

Children _____ Prisoners _____

Subjects who may be incompetent _____

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. Please describe how subject will receive Consent information:

3. Herbs/Devices

3a. Will Herbs be used? ___ Y ___ 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 ___ N

3f. Is it an investigational device? ___ Y ___ N

3g. 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? ? 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)

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:

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? __Y __N

6e. If yes, provide contact information.

7. Benefits

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

(a) Patient:

(b) 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 Dean of Research 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.

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)

Appendix G Sample PRAF

OREGON COLLEGE OF ORIENTAL MEDICINE
INSTITUTIONAL REVIEW BOARD
PROTOCOL REVISION/AMENDMENT FORM

This form is to be completed and attached to changes made to a research project. This includes any changes to the protocol, consent form or any supportive materials (as Investigator's Brochure, results from related studies or advertisements, etc.)

PRINCIPAL INVESTIGATOR:

STUDY:

=====

THE PROJECT HAS BEEN CHANGED AS FOLLOWS:

Protocol Modification (revision or amendment)

Consent Form Modification (revision or addendum)

Other (specify):

Does the change affect subject participation (e.g. procedures, risks, costs, etc.)

YES

NO

If yes, do subjects previously entered need to be notified of major changes?

BRIEF SUMMARY OF PROPOSED CHANGE(S) (or attach sponsor summary):

REASONS FOR PROPOSED CHANGES:

Principal Investigator

Date

For IRB use only

Reviewed on _____ by _____
date name signature

Approved? Y/N (circle one)

Appendix H HIPAA Authorization



OREGON COLLEGE of ORIENTAL MEDICINE

AUTHORIZATION FORM:

OREGON COLLEGE OF ORIENTAL MEDICINE

**AUTHORIZATION FOR THE CREATION, USE, AND DISCLOSURE OF
PROTECTED HEALTH INFORMATION FOR INSTITUTIONAL REVIEW BOARD
(IRB) APPROVED RESEARCH**

<i>Title of Study:</i>
<i>Name of Investigator:</i>
<i>Phone Number:</i>
<i>Sponsor:</i>
<i>IRB Approval Date:</i>
<i>IRB Study Number:</i>

This form authorizes Oregon College of Oriental Medicine to use and disclose certain protected health information about _____ (*Name of research subject*) that we will collect and create in this research study.

This authorization is voluntary, and you may refuse to sign this authorization. If you refuse to sign this authorization, your health care and relationship with OCOM will not be affected, however, you will not be able to enter this research study.

If you sign this form, you are agreeing that OCOM may use and disclose protected health information collected and created in this research study.

The specific protected health information to be disclosed are as follows:

<i>Health Information:</i>	<i>Purpose of disclosure:</i>
<input type="checkbox"/> Complete medical record	
<input type="checkbox"/> History and physical examination	
<input type="checkbox"/> Consultation Reports	
<input type="checkbox"/> X-Ray Reports	
<input type="checkbox"/> Laboratory Reports	
<input type="checkbox"/> Operative Reports	
<input type="checkbox"/> Discharge Summary	
<input type="checkbox"/> Progress Notes	
<input type="checkbox"/> Photographs, videotapes or digital or other images	
<input type="checkbox"/> Questionnaires, interview results, focus group survey, psychology survey, behavioral performance tests	

<input type="checkbox"/> Tissue and/or blood specimens	
<input type="checkbox"/> Other:	

Specially Protected Information:

The following highly confidential information will only be used and disclosed if you have placed your initials next to a specific category.

- _____ *HIV/AIDS information*
- _____ *Drug/alcohol diagnosis, treatment or referral information*
- _____ *Mental or behavioral health or psychiatric care*
- _____ *Genetic testing information*

The persons who are authorized to use and disclose this information are:

- All investigators listed on page one of the Informed Consent Form*
- Others at OCOM who are participating in the conduct of this research protocol*
- The OCOM Institutional Review Board*
- Others: _____*

The persons who are authorized to receive this information are:

- The sponsor of this study: _____*
- Federal or other governmental agencies responsible for research oversight (eg. FDA, OHRP):*

- Other: _____*

Protected health information that we collect from you in this study will be kept until:

- The study is completed*
- Indefinitely*
- Other: _____*

You have the right to revoke this authorization and can withdraw your permission for use of your information for this research study by giving the Principal Investigator (listed on the front of the consent form) your withdrawal *in writing*. The use and disclosure of your protected health information will stop on the date that the Principal Investigator receives your request. However, the Principal Investigator is allowed to use information collected before the date of the letter or collected in good

faith before your letter arrives. Revoking this authorization will not affect your health care or your relationship with OCOM.

While this study is in progress, you may not be given access to medical information about you that is related to the study. When the study is completed and the data analyzed, you will be permitted access to medical information collected about you during the study. You will also be told if this study has not collected any medical information about you.

Personal Health Information disclosed to a third party could possibly be released again without your permission. OCOM tries to protect against this by being very careful about releasing your personal health information. The ways in which we will try to limit the further release of your protected health information are:

- Contract agreements with those who may receive the information*
- Not releasing information in a way that could identify you*
- Other: _____*

You will receive a copy of this authorization after you sign it.

Printed name of research subject

Date

Signature of subject

Printed name of subject's representative

Date

Signature of subject's representative

Relationship to patient