Institutional Review Board Membership and Responsibilities

PURPOSE
This policy defines the membership, appointment and responsibilities of the Institutional Review Board (IRB)

SCOPE
All IRB Members, BCOM Agents, Faculty, Students and Staff involved in Human Subjects Research

RESPONSIBLE OFFICIAL(S)
Authorized Institutional Official for Research, Director of Research, IRB Chairperson

POLICY
The BCOM Institutional Review Board (IRB) is the administrative body at BCOM with authority to review and approve human subjects research conducted by BCOM investigators and students. The IRB is appointed by the Authorized Institutional Official for Research (IO) in compliance with 45 CFR 46.107 and at a minimum is composed of:

- At least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted at BCOM;
- Members of both sexes.
- Members representing more than one profession;
- Members representing biomedical and behavioral sciences;
- At least one member trained in and licensed to practice osteopathic medicine;
- At least one member whose primary concerns are in scientific areas;
- At least one member whose primary concerns are in nonscientific areas;
- At least one member who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution;
- Alternate members who are appointed to assume the responsibilities of regular members in the event that a regular member is unable to attend a meeting of the IRB.

Specific Duties of the IRB
Duties of the IRB are:

- Conducting initial and continuing review of research involving human subjects at intervals appropriate to the degree of risk, but no less than once a year.
- Reporting IRB findings and actions to the investigator and the institution.
- Determining the level of review required by a specific project, which projects require review more often than annually, and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.
- Reviewing proposed changes in research activities to insure that changes in approved research, during the period for which IRB approval has been given, has not been initiated without IRB review and approval.
- Requiring or waiving documentation of informed consent.
- Following procedures to insure that the IRB and Office for Human Research Protections (OHRP) of the Department of Health and Human Services (DHHS) receive reports of unanticipated problems involving risks to subjects and others.
- Monitoring additional safeguards when vulnerable subjects are involved in the research in order to protect against coercion or undue influence. Vulnerable subjects are defined as minors, mentally incompetent, prisoners, economically disadvantaged, educationally disadvantaged, and pregnant females.

- Conducting its review of research at convened meetings at which a quorum of the members of the IRB are present.
- Conducting reviews of all research protocols to determine which might be exempted from review. (Even review exempt protocols must be reviewed to ensure their non-exempt status.)
- Conducting reviews of all adverse event reports
- Approving research only with the concurrence of a quorum of those members in attendance.
- Reporting to the institution and OHRP any continuing or serious matters of non-compliance by investigators with the requirements and determination by the IRB.
- Having authority to suspend or terminate approval of research that is not in compliance with the IRB's determinations, or has been associated with unexpected serious harm or risks to subjects.

Categories of Membership

- Regular Members
  - Chairperson
  - Vice-Chairperson
  - Board Members
- Alternate Members
- Ex-Officio Members (non-voting)
- Ad Hoc IRB Consultants (non-voting)

Individual Member Responsibilities

Chairperson

- Appointed from the Regular Membership by the Authorized Institutional Official
- Term of appointment is for one year and is renewable
- Convene regular meetings of the IRB
- Convene special meetings of the IRB when necessary
- Assign primary and secondary reviewers on protocols
- Conducts review of all protocols discussed at convened meetings
- Conducts expedited review of research studies
- Review IRB policies and procedures on an ongoing basis. Recommend revisions to IRB as needed.

Vice-Chair

- Appointed from the regular membership by the Authorized Institutional Official in consultation with the Chairperson and the membership of the IRB.
- Term of appointment is for one year and is renewable.
- Performs duties of the chair in his/her absence
- Preside over meeting when chair has reason to recuse himself/herself from meeting deliberations
- Assist Chairperson and IRB staff as needed

Board Members

- Nominations for membership may be made by Department Chairs, Faculty Council, Staff Council, or self-nomination. Prospective members may also be identified by the IRB Chairperson and staff who are familiar with the nature and demands of the IRB.
- IRB members are appointed by the Authorized Institutional Official in consultation with the Director of Research.

- The initial term or appointment for the inaugural committee will be staggered between one to three years in order to establish a rotational membership with approximately one-third of the membership renewing each year. Subsequent terms of appointment are for three years. If a member resigns prior to the end of their term, a person may be appointed to complete the term of the member who vacated the position. Appointments are renewable.

Alternate Board Members

- Alternate Board Members may be appointed by the Authorized Institutional Official to serve as voting board members in instances when a regular board member is unable to attend the convened meeting of the IRB.
- The nomination, appointment, and term for Alternate Board Members is the same as for Board Members.

Ex Officio Members (Non-Voting)

- Individuals from among the academic or administrative staff of the University are appointed to aid the IRB in conducting its duties. These members may take part in all meetings of the IRB, participate in discussions and make recommendations, but they may not vote on the decisions. Ex-Officio Members are not included in determining or establishing a quorum at the meetings. IRB meeting minutes reflect the attendance or absence of Ex Officio members. The following individuals are standing ex-officio members of the IRB:
  - Institutional Official
  - IRB Administrative Staff

IRB Consultants (Non-Voting)

- The IRB at their discretion may invite individuals with particular expertise to serve as an *ad hoc* consultant when expertise is needed to assist in reviews that are deemed to require expertise beyond or in addition to that which is available on the IRB. Particular expertise needed may include scientific or discipline-specific knowledge, as well as knowledge about and/or experience working with, certain research topics or research populations. Consultants may be used for all aspects of IRB function including but not limited to initial protocol review, continuing review, reportable incidents, and protocol modifications. The IRB Chair and Institutional Official are responsible for identifying individuals with specific expertise and selecting the consultant when a consultant is deemed necessary by the IRB. Consultants to the IRB may not be selected if they have a conflict of interest with the protocol under review. No compensation is provided to the consultants. Consultants are only allowed to provide information to the committee and are not allowed to vote on the protocol decision.

Confidentiality Agreement

Upon appointment to the IRB or attendance at an IRB meeting, all members (voting and *ex-officio*), consultants, and guests will be asked to sign a confidentiality agreement.

Conflict of Interest Disclosure

No IRB member or consultant may participate in the IRB review of any project in which he/she has a conflict of interest, except to provide information requested by the IRB. Examples of conflict of interest may include: a member of the IRB who serves as an investigator or researcher on the protocol under review, or a member of the IRB who holds a financial conflict of interest in a sponsor or product under study. Members must indicate conflicts of interest as soon as possible after meeting materials are distributed by notifying the Chairperson of

the IRB, and must either recuse themselves (or abstain from deliberation and voting on the outcome of the protocol). The minutes of the IRB meeting record reflect the fact that member(s) were recused.

Orientation and Training of IRB Members:

Newly appointed IRB members are required to participate in an orientation session through the BCOM Office of Research that includes discussion of topics such as: research compliance, processing of protocols, meeting procedures, and expectations of member. In addition, new members will be instructed in the use of the IRB online site for members which includes the IRB policy manual, standard operating procedures, and relevant reference materials. All IRB members will also be required to successfully complete the online educational modules provided through the Collaborative Institutional Training Initiative (CITI) Program. Continuing education for IRB members will also be available throughout the year through the IRB online site as well as at regularly scheduled IRB meetings.

APPROVAL PAGE

Approved by: _____

Robert J. Ketchum, Ph.D.
Associate Dean, Academic & Pre-Clinical Affairs
Authorized Institutional Official for Research
Burrell College of Osteopathic Medicine

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