SECTION: Research and Sponsored Activity Policies — BCOM Policy B8540

TOPIC: BCOM Institutional Review Board — Approval Date: May 2016

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Approved: Signature on File

POLICY

The Burrell College of Osteopathic Medicine at New Mexico State Institutional Review Board #1 (IRB) shall be established as the authorized BCOM entity that functions to protect the welfare of human subjects used in research conducted by agents, students, and/or trainees of BCOM. Additionally, the BCOM IRB may fill this role for outside entities (educational institutions, research labs, healthcare systems, corporations, etc.) who contract with BCOM for this purpose. The BCOM IRB shall operate in full compliance with the U.S. Department of Health and Human Services, and U.S. Food and Drug Administration regulations for the protection of human subjects as described in 45 Part 46 and 21 CFR Parts 50 and 56 as outlined by the BCOM policies and procedures for the conduct of human research.

RESPONSIBLE OFFICIAL(S):

Authorized Institutional Official for Research, Director of Research, IRB Chairperson, IRB Members, IRB Staff.

DEFINITIONS

Research *defined by the federal regulations as "a systematic investigation, including research development, to develop or contribute to generalizable knowledge" [Federal Policy 45CFR46.102(d)].*

Human subjects *defined by federal regulations as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" [Federal Policy 45CFR46.102(d)].*

Agents *employees and non-employees who are conducting research when any of the following conditions exists:*

- *The researcher identifies as a BCOM faculty or staff member on any press releases, promotional pieces, or recruitment materials related to the study or research.*
- *The researcher affiliates with BCOM as an adjunct/courtesy appointee and identifies himself/herself as affiliated with BCOM on any press releases, promotional pieces, or recruitment materials related to the study or research.*
- *The researcher intends to publish and/or present the study findings at professional/public events and represent himself/herself as an agent of BCOM.*
- *The researcher is personally compensated by BCOM in any manner for this specific research, or the researcher receives BCOM funds in support of the specific research project.*
- *The researcher pursues and receives external funding for the specific research project using his/her BCOM status as support in securing the funding.*
- *The researcher is provided general salary support from BCOM when work on the research project is an expectation of the position description.*

Students *any individual enrolled in an academic program at BCOM or any student from another institution working under the guidance/tutelage of a BCOM agent on the research project.*

Trainees *any individual other than students who are working under the guidance/tutelage of a BCOM agent on the research project. Examples of trainees include postdoctoral fellows, interns, residents, and clinical fellows.*

PROCEDURES:

1. **Purpose of the BCOM Human Subjects Research Protection Program**
   The purpose of the Burrell College of Osteopathic Medicine Human Subjects Research Protection Program is to protect the rights and welfare of human subjects participating in biomedical and behavioral research. The BCOM Institutional Review Board (IRB) is the administrative body at BCOM with sole authority to review and approve human subjects research conducted by BCOM investigators and students, and may serve outside entities under contractual agreement. Specifically, the IRB functions to ensure that:
   - the rights and welfare of human subjects are paramount in the research process;
   - the highest standards of ethical conduct are employed in all human subjects research activities;
   - research investigators are properly trained in the ethical and regulatory aspects of research with human subjects;
   - research investigators inform human subject participants fully of procedures to be followed, the risks and benefits of participating in research, and of their right to withdraw from participation at any time;
   - research using human subjects at BCOM conforms with all applicable local state, and federal laws and regulations and specific policies of BCOM.

2. **Administrative Organization and Authority of the BCOM IRB**
   As an administrative body within BCOM, the IRB functions in coordination with other campus offices and committees. However, the IRB makes its independent determination whether to approve or disapprove a research protocol based upon whether or not human sub**jects are adequately protected. Approved research is subject to continuing IRB review and must be reevaluated at least annually. IRB jurisdiction applies to all Research involving Human Subjects at BCOM and BIHP&R. Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of BCOM or BIHP&R. However, those officials may not independently approve research involving human subjects.**

3. **Authorized Institutional Official**
   The Authorized Institutional Official, (IO), serves as the point of responsibility for the oversight of research and research related regulatory compliance which includes the IRB. Federal guidelines state that the IO should be an official of the institutio**n who has the legal authority to act and speak for the institution, and should be someone who can ensure that the institution will effectively fulfill its research oversight function. The CEO/President functions in this capacity but may choose to appoint an IO and delegate authority. If th**e CEO/President does not function as the Authorized Institutional Official, the delegated person should be the equivalent of the director of research and development, a dean or assistant dean, or hospital administrator. Examples of individuals who should not be appointed, since they cannot speak or act for the institution are: department chair, division heads, research coordinator, and so forth. The delegated IO may have the additional responsibility of selecting the chair of the IRB. Selection of appropriate personnel will assure the protection of the rights and welfare not only of research subjects, but also the institution itself.

4. **Authority of the BCOM IRB**
   The IRB has the authority to:
   - ensure that research conducted under its jurisdiction protects the rights, welfare and privacy of human subjects enrolled in research studies;
   - approve, require modifications in, or disapprove all research activities that fall within its jurisdiction based upon consideration for human subjects;
   - conduct continuing reviews of approved activities to protect the rights, welfare and privacy of research subjects;

- suspend or terminate approval of research or studies that fall under its jurisdiction;
- place restrictions on research or studies that fall under its jurisdiction.

Inappropriate attempts to influence the IRB process, individual IRB members, or IRB staff will be reported to the Authorized Institutional Official. The IO will respond to and stop any attempt at inappropriate influence of the IRB, and has the authority to limit or remove an agent's, student's or trainee's ability to conduct research.

5. **Jurisdiction of the BCOM IRB**

The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the Burrell College of Osteopathic Medicine (BCOM).

The IRB has the authority to review all research involving human subjects regardless of the source of funding and/or location of the research if:

- The research is sponsored by BCOM.
- The research is conducted by BCOM agents, students, or trainees
- The research is conducted by or under the direction of any agent, student, or trainee of BCOM using any property or facility of BCOM.
- The research is conducted by Investigators in institutions in which the IRB has an authorization agreement in place.

6. **IRB Guiding Principles and Ethical Mandates**

The ethical principles guiding the BCOM IRB are based on the following documents:

a. The Nuremberg Code: The modern history of human subject protections begins with the discovery after World War II of numerous atrocities committed by Nazi doctors in war-related human research experiments. The Nuremberg Military Tribunal developed ten principles as a means of judging their "research" practices, known as The Nuremberg Code. The significance of the Code is that it addressed the necessity of requiring the voluntary consent of the human subject and that any individual "who initiates, directs, or engages in the experiment" must bear personal responsibility for ensuring the quality of consent.

b. The Declaration of Helsinki: Similar principles to The Nuremberg Code have been articulated and expanded n later codes, such as the W arid Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects (1964, revised 197 5, 1983, 1989, 1996, 2000, 2013), which call for prior approval and ongoing monitoring of research by independent ethical review committees.

c. The Belmont Report: On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines, which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider:

i) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine;
ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects;
iii) appropriate guidelines for the selection of human subjects for participation in such research; and
iv) the nature and definition of informed consent in various research settings.

The Belmont Report which was entered into the Code of Federal Regulations, and is divided into three parts: Part A; Boundaries Between Practice & Research, Part B; Basic Ethical Principles, and Part C: Applications.

The Belmont Report refers to "basic ethical principles" as general judgments that serve as a basic

justification for the many particular ethical prescriptions and evaluations of human actions. 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 of persons, beneficence and justice.

- **Respect for Persons:** Application of this principle includes obtaining informed consent, protection of individual privacy, confidentiality, and protection of vulnerable populations.
- **Beneficence**: Application of the principle of beneficence includes consideration of the risks and benefits of the research. Two general rules have been formulated as complementary expressions of beneficent actions in human subjects research:
  - do not harm; and
  - maximize possible benefits and minimize possible harms.
- **Justice:** The principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

CROSS REFERENCES: