

3359-47-11 Protection of human subjects.

(A) University institutional review board.

- (1) A university "Institutional Review Board for the Protection of Human Subjects" (IRB) shall be appointed by the vice president for research and dean of the graduate school. All protocols, projects or proposals prepared by university personnel or university students that involve human subjects shall be reviewed by the IRB.
- (2) The IRB shall be composed of at least five members. IRB members shall have varied backgrounds and expertise. Membership shall be diverse, including consideration of race, gender and cultural backgrounds. At least one member shall have nonscientific areas as a primary concern. At least one member will be non-affiliated with the university. Members of the IRB shall be appointed for terms of three years.
- (3) The IRB shall develop policies, procedures and programs related to human subject protections at the university of Akron consistent with applicable laws and regulations such as the "Belmont Report," a publication of "The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research;" 45 C.F.R. 46; and the university's federal-wide assurance. Unless otherwise required by law or applicable regulations, the IRB shall review such policies and procedures annually and implement changes that are appropriate and necessary.
- (4) The IRB represents the interests of the subjects, thus has the ultimate authority over human subjects study at the university of Akron. No other university office or official may approve research involving human subjects that has not been approved by the IRB. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the vice president for research and dean of the graduate school. However, the vice president for research and dean of the graduate school shall not be authorized to approve research if it has not been approved by the IRB.

(B) IRB chair.

- (1) An IRB chair shall be appointed by the vice president for research and dean of the graduate school to implement the human subject protections program at the university of Akron. The chair shall ensure that human subject protection activities are performed at the university of Akron in accordance with approved policies and regulatory requirements.
- (2) Duties of the chair.
 - (a) Establish and implement, in conjunction with the university IRB, written policies

and procedures for the protection of human subjects.

- (b) Establish and implement, in conjunction with the university IRB, training and educational experiences for university personnel and students on the protection of human subjects.
 - (c) Investigate deviations from human subject protections policies and procedures and implement corrective actions as necessary.
 - (d) Approve or disapprove changes in human subject protections policies and procedures with the advice and consent of the university IRB.
 - (e) Provide a written briefing on the human subject protections program at the university of Akron to the vice president for research and dean of the graduate school on an annual basis. In addition the chair, or designee, shall make monthly reports of activities to the IRB.
- (C) Compliance with human subject protection laws, regulations and policies.
- (1) All university personnel and students shall cooperate fully with the policies and procedures implemented by the university IRB to provide protections to human subjects.
 - (2) Violations of law, regulation, or university policies respecting human subject protections will be considered serious matters, which may warrant sanctions or more serious action, such as suspension of research protocols, termination of research protocols, and loss of research privileges, as the situation may warrant, including investigation for scientific misconduct.
- (D) An IRB policies and procedures manual as required by federal regulation shall be available to all researchers in print as well as through a link at the office of research administration website.

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Ted A. Mallo
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