

August 30, 2011

This information is being provided in response to requests from study sponsors for information about the membership and function of the IRB at National Jewish Health.

National Jewish Health has an approved Federal Wide Assurance (FWA00000778) on file with the U.S. Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP). This FWA expires March 10, 2012.

The following IRBs are registered with OHRP and are designated in the National Jewish Health FWA to conduct reviews of research involving human subjects for National Jewish Health:

- National Jewish Health IRB (IRB00000024)
- Colorado Multiple IRB (IRB00000650, IRB00000651, IRB00002760, IRB00000648)
- Quorum Review Inc. (IRB00003226)
- Western IRB (IRB00000533)

Additionally, the NJH IRB serves as the IRB of record for select types of studies conducted at the University of Colorado, Denver and HCA-HealthONE LLC pursuant to cooperative agreements.

All research involving human subjects reviewed by the NJH Institutional Review Board is guided by the ethical principles in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*. The IRB is duly constituted, fulfilling Federal requirements for membership; has written procedures for initial and continuing review for human subjects research; prepares written minutes of convened meetings; and retains records pertaining to the review and approval process all in compliance with the requirements for IRBs defined in DHHS 45 Code of Federal Regulations (CFR) Parts 46 and 164, Food and Drug Administration (FDA) 21 CFR Parts 50 and 56, and Guidelines of the International Conference on Harmonization relating to Good Clinical Practices (GCPs) to the extent required by the FDA.

The NJH IRB does not release names of IRB members. The most current redacted roster is available on the IRB website. Older redacted rosters are available upon request. Any IRB member who is an investigator, co-investigator or has any other conflict of interest with a protocol under review by the NJH IRB will not participate in the deliberation or vote of that protocol although he or she may be called upon to answer questions during the review.

If you have any other questions about committee membership or function, please call the IRB office at (303) 398-1477.

Thank you,

Wendy Charles, MS., CIP, CCRP
Director, Research Regulatory Affairs