



Charlie Crist

Ana M. Viamonte Ros, M.D., M.P.H.

Governor

State Surgeon General

Florida Department of Health Statement of Compliance

Florida Department of Health maintains a written assurance of compliance with the Office for Human Research Protections (OHRP). The assurance number is FWA00004682. The Florida Department of Health maintains two IRBs; both are registered with OHRP and FDA:

- IRB00000456 - State of Florida Dept of Hlth IRB #1 (OHRP/FDA)
- IRB00005334 - State of Florida Dept of Hlth IRB #2 (OHRP/FDA)

DOH's IRBs are duly constituted, have written procedures for initial review, review of modifications, and continuing review of research. DOH prepares written minutes of convened meetings, and retains records pertaining to the review and approval process, all in compliance with requirements of FDA regulations 21 CFR Parts 50 and 56, FDA GCP regulations, and DHHS regulations 45 CFR 46. DOH applies Subpart A of the Common Rule to all research, and Subparts B, C, and D to federally-sponsored research, with substantially equivalent protections for review of all other research involving pregnant women, prisoners, and children. DOH also reviews in compliance with other applicable federal and state laws and regulations governing IRBs and research with human beings, such as EPA regulations.

Since 2008, the Florida Department of Health's human research protection program has been fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

If you have questions or need further information, please do not hesitate to contact us.

Sincerely,



A handwritten signature in black ink, appearing to read "Robert Hood".

Robert Hood, Ph.D.
State Public Health Ethicist
Florida Department of Health

Federal Wide Assurance#: 00004682