

September 16, 2015
1:30-3:00 PM



Department of Health
2585 Merchants Row
Conference Rm. 310 A
Tallahassee, Florida 32311

IRB 1 Convened Committee Meeting Minutes

IRB Attendance:

Sandra Schoenfisch (Chair, Expertise in Subpart D: Children)
Ron Brown (Non-Scientist, Non-Affiliated, Present by Phone)
Daphne Holden
Roland Reis (Non-Scientist)

Members absent:

Ovidiu Cotea (Absent)
Becky Grigg (Absent)

Other Attendees: Robert Hood, Ph.D., HRPP staff.

Quorum

A quorum was not present. No actions were taken.

Announcements

Dr. Hood made the following announcements:

- Staffing changes
 - Dr. Sharon Watkins resigned as the Director of the Research Unit.
 - Derek Schwabe-Warf was re-assigned from the HRPP is now the staff contact for the Department's biomedical research programs. The biomedical research programs fund researchers at Florida universities and research institutes to conduct research involving cancer, tobacco-related diseases, and Alzheimer's disease.
 - Dr. Hood is assigned to the Human Research Protection Program. There is one FTE devoted to the Human Research Protection Program, including support for the IRB.
- IRB member appointments are on hold. HRPP staff communicated the challenges meeting quorum to the contacts for the board and council approval process.
- The procurement process for an electronic system is in process. After a review of systems in the market the Department is pursuing an existing off-the-shelf system that is specifically designed

for IRB review. A number of these systems require an up-front cost to configure the system in the initial year. Program staff requested an additional \$25,000 for one-time setup of an electronic system. After the first year of initial set-up the annual costs are expected to fall within the current program budget.

- The AAHRPP process is delayed because of difficulty obtaining approval from the Department of Financial Services to pay the fee. The paperwork to authorize payment was initially submitted in June; payment was authorized without delay since 2006 at least. AAHRPP received the check for full payment on September 15, 2015. We anticipate the next step will be to select a date for the site visit.

Education:

Dr. Hood reviewed the history of FDA regulation of human participant protections, and the work of Frances Oldham Kelsey in the Thalidomide tragedy and subsequent improvements in human participant protections.