

January 7, 2015  
9:00-11:00 am



Department of Health  
2585 Merchants Row  
Conference Rm. 345Q  
Tallahassee, Florida 32311

## IRB#2 Convened Committee Meeting Minutes

---

### **IRB1 Attendance:**

Carina Blackmore (Chair) (Absent)  
Jaime Arango (present by phone, non-scientist, non-affiliated)  
Daniela Chiriboga Salazar (present by phone)  
Cheryl Clark (absent)  
Jamie Forrest  
Nkechi Ichite (present by phone)  
Nina McGrew (present by phone)  
Daniel Thompson  
Brenda Whittenberg

---

A quorum **was** present.

The quorum is defined as a majority of members present. The quorum also reflected the requirement outlined in 45 CFR 46.108 as well as 21 CFR 56.107. Please note that the number of members present will not always match the total number of votes on items as the total number votes reflects the number of members present in the room at the time of discussion and vote. At least one non-scientist and at least one non-affiliated member were present.

### **Other Attendees:**

Sarah Hofmeister, Research Program Analyst, Public Health Research Unit  
Robert Hood, Ph.D., Manager, Public Health Research Unit

### **Attendance Notes:**

Conflict of Interest: none declared

Members did not report any:

- Ownership interest, stock options, or other financial interest related to the research of any value.
- Compensation related to the research of any value.

- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Board or executive relationship related to the research, regardless of compensation.
- Interest that could be affected by the outcome of the research.

Attendance Note: Chiriboga Salazar, Arango, Ichite, McGrew, Whittenberg were present by phone. Members present by phone received all pertinent material through the IRB management system prior to the meeting to allow adequate time for review and request of additional information, if needed. Members present by phone actively and equally participated in the discussion of all protocols.

#### **Education:**

Dr. Robert Hood provided continuing education on the process for the Department's re-accreditation application to the Association for Accreditation of Human Research Protection Programs, and discussed plans for the IRB application management system.

Submissions for review Full Board Review (1)

**Protocol Title:** Clofazimine use in the treatment of Leprosy  
Clofazimine use in the long-term treatment of leprosy, Phase III  
**P.I.-David Ashkin**

**Description:** Research continues, including interactions or interventions. There are currently 3 active participants in the study. No reportable events have occurred in this review period.

**Meeting Discussion:** A reviewer presented a summary of the protocol, followed by discussion. All committee members reviewed protocol documents. This is a continuing review submission for a previously approved protocol.

No reportable events have occurred in this review period. One patient completed the study.

The Committee provided rationale for the basis of IRB approval under 45 CFR 46.111 and 21 CFR 56.111:

There are three patients enrolled at the local site. There have been no problems and the study is progressing normally at this site. Risks continue to be minimized by using procedures consistent with

sound science, and are reasonable compared with other drugs in the class. Risks are reasonable in relationship to the importance of the knowledge to be obtained. There were no changes to the consent document or procedures. The PI or co-PI obtain consent in private exam rooms. There was one addendum to the consent providing an update on safety information, reviewed previously. There were no changes to recruitment, or monitoring, or the provisions to protect the privacy interests of participants and the confidentiality of participants' data. There are no vulnerable populations enrolled in the study.

Motion: Approve this continuing review as greater than minimal risk for 12 months.

Total votes for approval: (Total members voting: 6) Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

**Next Meeting: February 4, 2015 9:00 a.m.**

**Other business: None**