

November 28, 2018  
1:30-3:00 PM



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

## IRB 1 Convened Committee Meeting Minutes

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### **IRB Attendance:**

Sandra Schoenfisch (Chair, Expertise in Subpart D: Children) (non-affiliated)  
Shoshana Levy (Present by phone)  
Bob Eadie (non-scientist) (Present by phone)  
Barbara Frentzen (Present by phone) (non-affiliated)  
Karen Card (Co – Chair)

### **Absent:**

Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent)  
Ovidiu Cotea  
Daphne Holden  
Megan Macdonald (Expertise in Subpart D: Children)

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**Other Attendees:** Rotanya Bryan, MPA, Gavin Grigg, and Bonnie Gaughan-Bailey, MPA

### **Quorum**

A quorum was present. A quorum is defined as the majority of the IRB members and representation of each of the members as identified in the requirements outlined in 45 CFR 46.108 as well as 21 CFR 56.107. At least one non-scientist and at least one non-affiliated member were present.

### **Approval of Previous Minutes:**

Minutes from the October 17, 2018 meeting were circulated by email and modified by member input.

### **Conflict of Interest:**

Conflict of Interest: None declared

Members did not report any:

- Compensation or payments for services (e.g., consulting fees, lecture payments, bonus, royalties, paid authorship, honoraria, gifts, or in-kind products or services) related to the research of any value, except as otherwise excluded by this policy.
- Compensation or payments for services where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
- Equity interests (stocks, stock options, security, or other ownership interests) related to the research of any value.
- Equity interests whose value when aggregated for the individual and the individual's immediate family represents more than a five percent ownership interest in any single entity.
- Equity interest related to the research in a non-publicly traded corporation of any value by the individual or a member of the individual's immediate family
- Equity interest related to the research of any amount to the researcher or any member of the researcher's immediate family where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
- Intellectual property rights and interests (patents, copyrights, royalties, licensing agreements, and any other proprietary interest related to the research).
- Board or executive relationship related to the research, regardless of compensation.
- Involvement or participation in the design, conduct, or reporting of the research, including providing advice on Department registry data systems.
- Serving as the immediate supervisor of a researcher within the last year
- Any other interest that the IRB member believes would interfere with his or her ability to objectively review a protocol.
- Any travel related to research

**Education:**

Rotanya Bryan discussed the roles and responsibilities of the board. She outlined what the overarching mission of the board is and how that may conflict with the institution. She also apprised the members of Common Rule revisions and how that will impact the board as well as the Department.

**Protocol Title:** A double blind randomized placebo controlled multicenter study to evaluate safety tolerability and efficacy on LDL-C of Evolocuamab (AMG 145) in Subjects with HIV and with Hyperlipidemia and or mixed dylipiedemia (#170015HD) (Florida Department of Health)

**Submission:**  
(Modification)

**Principal Investigator:**  
Morano, Jamie MD

**Presenters:**  
Levy, Shoshana MD, MPH  
Frentzen, Barbara MSN, ARNP

**Meeting Discussion:** This is study intends to evaluate the safety and tolerability and efficacy on LDL-C of Evolocuamab in subjects HIV and with Hyperlipidemia and or mixed dylipiedemia by conducting a double-blind randomized placebo controlled multicenter site. The investigator submitted an amendment to the Investigator Brochure (IB) to include Minor editorial/style changes (that do not affect results/conclusions) were made throughout the document to align with Amgen style, format, and

template, ie, proper use of abbreviations/acronyms nonbreaking hyphens and spaces, proper ordering and format of table footnotes, etc.

Board members found no new change in risk. However, they did note that angioedema was a risk included in the IB. The primary presenter found the modifications to the IB to be acceptable and the secondary presenter seconded.

Total votes to approval: Affirmative:5 Negative: 0 Recusal:0 Absent:4

Next Meeting: December 19, 2018

Other Business: None

Meeting Adjourned: 2:00pm