June 17, 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)
Ovidiu Cotea (Present by phone)
Becky Grigg
Daphne Holden
Roland Reis (Non-Scientist)

Other Attendees: Derek Schwabe-Warf, Robert Hood, Ph.D.

Quorum

A quorum was present. A 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.

Members present by phone received all pertinent materials 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.

Approval of Previous Minutes:

Minutes from the 05/20/2015 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:

Robert Hood presented a didactic presentation on the requirements concerning protocol-specific justifications. Protocol specific justifications are mandatory for waivers or alterations of consent in addition to research involving children, pregnant women, or prisoners.

Protocol Title: Strategic Timing of AntiRetroviral Treatment (START) Orange CHD

Submission:	**Principal Investigator:**	**Presenters:**
Modification	Nila Desai, M.D.	Ovidiu Cotea
		Ron Brown

Meeting Discussion: This greater than minimal risk study looks at the effects of ART on HIV. Specifically, it examines if starting ART as soon as HIV is detected affects viral load, HIV related incidence, and side effects. Current international treatment guidelines vary concerning the practice of postponing ART vs

starting immediately following HIV detection. Some countries recommend starting ART immediately while others recommend waiting to start ART until T-Cell counts drop below 500. This study aims to use evidenced based results to provide standardized international guidelines on ART starting times. This modification serves as a notification to the IRB from the DSMB that the participants delaying ART had statistically significant higher viral loads and a greater incidence of HIV related events compared with those starting ART as soon as HIV was detected. All participants will be notified of this DSMB report and asked to switch over to ART if they have not begun yet. The studies will remain open to track both groups as the group that didn't start ART early begins to be placed on ART. At this specific site, three participants were in the deferred/delayed arm (no ART treatment). Recruitment for this study has been stopped.

Reviewers determined the modifications to this greater than minimal risk study changed the research design because the deferred arm was dropped. The research design is still sound since participants in both arms will continue to be monitored. The modifications do not add new risks or change the probability or magnitude of existing risks, which were previously determined to be reasonable. The modification does not change participant selection procedures because participant recruitment has stopped. The modification does not change the consent procedures, which continue to be appropriate. The modification changed plans for safety monitoring because the DSMB recommended stopping the deferred arm but will still be monitoring all participants as they switch into ART. This means that the study endpoints have changed in regards to DSMB monitoring. There were no modifications to protections for privacy interests or confidentiality protections. The modification did not change inclusion criteria; there are no vulnerable populations are enrolled in the study.

Total votes for approval: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

Protocol Title: Strategic Timing of AntiRetroviral Treatment (START) Hillsborough CHD

Submission:	**Principal Investigator:**	**Presenters:**
Modification	Charurut Somboonwit, M.D.	Ovidiu Cotea
		Ron Brown

Meeting Discussion: This greater than minimal risk study looks at the effects of ART on HIV. Specifically, it examines if starting ART as soon as HIV is detected affects viral load, HIV related incidence, and side effects. Current international treatment guidelines vary concerning the practice of postponing ART vs starting immediately following HIV detection. Some recommend starting ART immediately while others recommend waiting to start ART until T-Cell counts drop below 500. This study aims to use evidenced based results to provide standardized international guidelines on ART starting times. This modification serves as a notification to the IRB from the DSMB that the participants delaying ART had statistically

significant higher viral loads and a greater incidence of HIV related events compared with those starting ART as soon as HIV was detected. All participants will be notified of this DSMB report and asked to switch over to ART if they have not begun yet. The studies will remain open to track both groups as the group that didn't start ART early begins to be placed on ART. At this specific site, three participants were in the deferred/delayed arm (no ART treatment). Recruitment for this study has been stopped.

Reviewers determined the modifications to this greater than minimal risk study changed the research design because the deferred arm was dropped. The research design is still sound since the deferred arm had higher incidence of HIV related incidence and participants in both arms will continue to be monitored. The modifications do not add new risks or change the probability or magnitude of existing risks, which were previously determined to be reasonable. The modification does not change participant selection procedures because participant recruitment has stopped. The modification does not change the consent procedures, which continue to be appropriate. The modification changed plans for safety monitoring because the DSMB recommended stopping the deferred arm but will still be monitoring all participants as they switch into ART. This means that the study endpoints have changed in regards to DSMB monitoring. There were no modifications to protections for privacy interests or confidentiality protections. The modification did not change inclusion criteria; there are no vulnerable populations are enrolled in the study.

Total votes for approval: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

Next Meeting: 07/15/2015

Other Business: None

Meeting Adjourned: 2:10 pm