October 7, 2015
9:00-10:30 am

Department of Health
2585 Merchants Row
Conference Rm. 320P
Tallahassee, Florida 32311

IRB 2 Convened Committee Meeting Agenda

IRB Attendance:

Carina Blackmore (Chair)

Jaime Arango (non-scientist, non-affiliated)

Daniela Chiriboga Salazar

Cheryl Clark (Expertise in Subpart B: Pregnant Women/Fetus/Neonates; and Subpart D: Children)

Jamie Forrest

Nkechi Ichite

Nina McGrew (Non-affiliated)

Brenda Whittenberg (Expertise in Subpart C: Prisoners, non-affiliated)

Other Attendees:

Robert Hood, Ph.D, Public Health Research Unit

Derek Schwabe-Warf, Public Health Research Unit

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.

Conflicts of interest: no reportable interests

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:

Dr. Hood reviewed the history of FDA regulations and development of FDA's system for protecting participants in research, created through the work of long-time FDA official Frances Oldham Kelsey. She was a physician who worked for the FDA. Among her accomplishments were the fact she personally prevented the approval of thalidomide (Kevadon) in the US. She created and led the first surveillance and drug safety unit at the FDA, and was active throughout her career. At 81 years of age she was named Deputy for Scientific and Medical Affairs at the FDA, and finally retired from the FDA in 2005 at age 90. She died August 7, 2015 – 101 years old.

Notification of Reviews Using the Expedited Procedure:

A spreadsheet was distributed that listed 24 studies reviewed between July 1 and September 30 for both IRBs

- Mean days from submission to approval: 28
- Standard Deviation: 25 days

Submissions for Convened Board Review (#):

(1) Protocol Title: Study of Geographic Distribution of ALS cases in Florida Surveillance Program in Relation to Environmental Risk Factors

Note: Please see the file "Bradley's Response to IRB Questions 8-12-2015" in the packet.

Submission:	**Principal Investigator:**	**Presenters:**
Initial Review	Walter Bradley DM, FRCP	Carina Blackmore Cheryl Clark

Meeting Discussion:

The researcher is applying for initial review. Procedures in the research are not greater than minimal risk, but the reviewer using the expedited procedure requested additional information in order to determine if the criteria for approval are met and requested the convened IRB review. The study proposes to examine a potential connection between exposure to cyanobacteria and ALS. However, there are significant limitations to the design, and while it meets minimal standards for sound science in comparison with other ecological study designs, it suffers from some of the same types of problems. For example, there is limited information in the database about exposure – how far people may have been to waterways, and how much time people may have been exposed to cyanobacteria.

The IRB previously requested the researcher provide plan for community engagement to improve understanding of the limitations of the research, and the researcher has provided a plan to work with ALS support groups.

The Committee provided rationale for the basis of IRB approval under 45 CFR 46.111 and 21 CFR 56.111: (1) Reviewers determined this ecological study is consistent with sound research design in terms of similar studies, which are useful only as hypothesis-generating studies, and does not unnecessarily expose subjects to risk. (2) Risks are reasonable in relation to anticipated benefits. (3) Selection of subjects is equitable: the study involves secondary analysis of existing data collected as part of a pilot of an ALS disease registry. (4) The study involves secondary analysis of existing data. The data was not collected for this purpose. The IRB determined a waiver of consent was appropriate. (5) The study does not present greater than minimal risk, and so the researcher's monitoring of safety is adequate. (6) Committee members discussed the provisions protecting privacy interests in the application and determined that adequate provisions were made to protect the privacy of participants. (7) Committee members discussed the provisions protecting confidentiality interests in the application and determined that adequate provisions were made to protect the confidentiality of data. Adequate effort will continue to be made to keep subject's information confidential. (8) There are no vulnerable populations in the research.

(2) Protocol Title: HAART Standard Version of the PROMISE Study (Promoting Maternal and Infant Survival Everywhere) Version 2.0

Submission:	Principal Investigator:	Presenters:
Modification	Patricia Emmanuel, M.D.	Daniela Chiriboga-Salazar Nkechi Ichite

Meeting Discussion: A reviewer presented a summary of the study followed by discussion. The primary purpose of the study is to determine whether continuation of HAART postpartum reduces morbidity and mortality among women receiving HAART for PMTCT when compared to HAART discontinuation and re-initiation according to current standards of care. The primary combined endpoint includes death, AIDS-defining illness, and serious non-AIDS-defining cardiovascular, renal, and hepatic events. Subjects will be randomized to one of the following two treatment arms; Treatment Arm A: Continuation of HAART postpartum or Treatment Arm B: Discontinuation of HAART postpartum.

The study is progressing normally, and is closed to enrollment. Remaining participants will be seen every three months through the conclusion of the study. Researchers have enrolled three participants at the local site, and one participant was withdrawn because researchers lost contact. There have been no new risks or benefits in the research, and no scientific publications, safety monitoring reports, interim findings, multi-center trial reports, changes in standard of care, or any similar reports relevant to the risks or potential benefits of this study or that suggest the risks or potential benefits of the study may have changed. There have been no problems in the previous review period.

The Committee provided rationale for the basis of IRB approval under 45 CFR 46.111 and 21 CFR 56.111: (1) Reviewers determined the study continues to be consistent with sound research design and does not unnecessarily expose subjects to risk. (2) Risks are reasonable in relation to anticipated benefits. All participants have been transitioned to the treatment arm. (3) Selection of subjects continues to be equitable. The study is closed to enrollment. (4) The Investigator has chosen long form written consent, which is appropriate for this study. There have not been any changes to the process of obtaining informed consent. (5) Committee members discussed the safety monitoring plan in the application and determined that adequate provisions were made for safety monitoring. No changes have been made to safety monitoring plan since the last approval period. (6) Committee members discussed the provisions protecting privacy interests in the application and determined that adequate provisions were made to protect the privacy of participants. To enhance protection of privacy, the researchers have obtained a Certificate of Confidentiality from the National Institutes of Health. (7) Committee members discussed the provisions protecting confidentiality interests in the application and determined that adequate provisions were made to protect the confidentiality of data. HIPAA disclosures are present. Adequate effort will continue to be made to keep subject's information confidential. (8) The study involves pregnant women; safeguards are in place for the rights and welfare of vulnerable populations. The risk to the fetus is caused solely by interventions or procedures that hold out the prospective of direct benefit for the woman or fetus. Both arms of the study receive HIV treatment, consistent within existing variations in existing standard of care. The risk is the least possible to achieve the objectives; research involves procedures which are within the range of standard of care. Research holds out the prospect of direct benefit to both the pregnant woman and the fetus because it is designed to improve the quality of HIV care. Consent of the mother is obtained, and the consent process includes appropriate disclosures on the foreseeable impact of the research on the fetus. No inducements have been offered to terminate pregnancy for purposes of the research.

(3) Protocol Title: EGRIFTA LTO Study A Phase 4, observational, multicenter, 10-year prospective cohort safety study comparing subjects with HIV-associated abdominal liophypertrophy exposed to EGRIFTA (tesamorelin for injection) to a similar group of subjects not exposed to EGRIFTA

Submission:	**Principal Investigator:**	**Presenters:**
Continuing Review	Ewa Szczypinska, M.D.	Daniela Chiriboga-Salazar Nkechi Ichite

Meeting Discussion: A reviewer presented a summary of the study followed by discussion. This is a long-term study to monitor EGRIFTA for side effects such as HIV-associated increases in abdominal body fat. The study is progressing normally, and is closed to enrollment. Researchers have enrolled 18 participants at the local site. Five participants acquired insurance under the affordable care act and elected to receive the immunology care within the private sector of the community. There have been no new risks or benefits in the research, and no scientific publications, safety monitoring reports, interim findings, multi-center trial reports, changes in standard of care, or any similar reports relevant to the risks or potential benefits of this study or that suggest the risks or potential benefits of the study may have changed. There have been no problems in the previous review period.

The Committee provided rationale for the basis of IRB approval under 45 CFR 46.111 and 21 CFR 56.111: (1) Reviewers determined the study continues to be consistent with sound research design and does not unnecessarily expose subjects to risk. (2) Risks are reasonable in relation to anticipated benefits. All participants have been transitioned to the treatment arm. (3) Selection of subjects continues to be equitable. The study is closed to enrollment. (4) The Investigator has chosen long form written consent, which is appropriate for this study. There have not been any changes to the process of obtaining informed consent. (5) Committee members discussed the safety monitoring plan in the application and determined that adequate provisions were made for safety monitoring. No changes have been made to safety monitoring plan since the last approval period. (6) Committee members discussed the provisions protecting privacy interests in the application and determined that adequate provisions were made to protect the privacy of participants. To enhance protection of privacy, the researchers have obtained a Certificate of Confidentiality from the National Institutes of Health. (7) Committee members discussed the provisions protecting confidentiality interests in the application and determined that adequate provisions were made to protect the confidentiality of data. HIPAA disclosures are present. Adequate effort will continue to be made to keep subject's information confidential. (8) There were no vulnerable populations.

(4) Protocol Title: GS- 0119 A Phase 3 open-label study to evaluate switching from optimized stable antiretroviral regimens containing darunavir to elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) single tablet regimen (STR) plus Darunavir (DRV) in treatment experienced HIV-1 Positive adults

Submission:	**Principal Investigator:**	**Presenters:**

Continuing Review	Todd Wills, M.D.	Daniela Chiriboga-Salazar Jaime Arango

Meeting Discussion: A reviewer presented a summary of the study followed by discussion.

Description

The study is progressing normally, and is closed to enrollment. Remaining participants will be seen every three months through the conclusion of the study. Researchers have enrolled one participant at the local site, who continues on study. There have been no new risks or benefits in the research, and no scientific publications, safety monitoring reports, interim findings, multi-center trial reports, changes in standard of care, or any similar reports relevant to the risks or potential benefits of this study or that suggest the risks or potential benefits of the study may have changed. There have been no problems in the previous review period.

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(5) Protocol Title: MK-1439-007 Multicenter, Double-Blind, Randomized, 2-Part, Dose Ranging Study to Compare the Safety, and Antiretroviral Activity of MK-1439 plus Truvada versus Efavirenz plus Truvada in Antiretroviral Treatment Native, HIV-1 Infected Patients

Submission:	**Principal Investigator:**	**Presenters:**
Continuing Review	Jose Montero, M.D.	Daniela Chiriboga-Salazar Jaime Arango

Meeting Discussion: A reviewer presented a summary of the study followed by discussion.

Description

The study is progressing normally, and is closed to enrollment. Remaining participants will be seen every three months through the conclusion of the study. Researchers have enrolled one participants at the local site, who continues in the study. Participant selection and enrollment continues. There have been no new risks or benefits in the research, and no scientific publications, safety monitoring reports, interim findings, multi-center trial reports, changes in standard of care, or any similar reports relevant to the risks or potential benefits of this study or that suggest the risks or potential benefits of the study may have changed. There have been no problems in the previous review period.

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