

Meeting Date: May 6, 2020
Next Meeting: June 3, 2020

Attendance:

Jamie Forrest, M.S. (CHAIR)
Julia Fashner, M.D.
Nkechi Ichite, Pharm.D., Ph.D.
Karen Card Ph.D

4 needed for quorum

Quorum:

A quorum **was** present.

The quorum is defined as a majority of members present, **one member whose primary interests are non-scientific, and one member who is not affiliated, and whose immediate family are not affiliated with DOH.** 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:

Andrew Wentzell, IRB Coordinator
Gavin Grigg, IRB Analyst
Robin DeWalt, Biomedical Scientific Advisor
Bonnie Gaughan-Bailey, Administrator, Office of Public Health Research

Attendance Notes:

Conflict of Interest: **None**

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: Due to COVID-19, all IRB members were present by phone. Members present by phone received all pertinent material through IRB Manager 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.

Old Business: **None**

Other Business: **There was no other business discussed at this meeting.**

Notes: Applications reviewed and approved using the expedited procedure and exempt studies and non-research determinations were reported in the meeting agenda in IRB Manager; there were no questions or discussions about these actions.

New Business:

eHARS HIV database registry for educational series – Loraine Maddox MPH

Continuing Board Review:

Protocol Title: Clofazimine use in long term treatment of leprosy for the FDOH

Andy: Review form was not submitted by Jamie Arango as we were anticipating so we have to table this study unless someone else has a recommendation.

Karen Card: These studies are ongoing and will continue under emergency use anyway, and they are of such long

standing and so familiar to everyone that has reviewed them that we should not indicate that the activity should stop, because ultimately these people are receiving a medical standard of care for a disease. Karen did not think that our IRB should interfere with this study.

Bonnie: Lead presenter will present to us and we can make a motion on whether to continue the study and approve the study pending the review of the additional feedback from Jamie Arango. Further, she suggested we could have the motion that it is approved unless feedback from Jamie indicated a different motion. Certainly, emergency use would apply here too.

Dr. Ichite: Just reviewed in Jan and the study should continue. We should not stop the study.

Fashner, Julia is primary reviewer: This study was started back in 2006 and patients that had leprosy they were given chlofazimine. There has ever only been one patient who has been enrolled in the study, in the past year no one has been enrolled and no adverse events have been reported. This is a study where we need to know if there are any new patients or not and, in her opinion, it can be continued to be approved until next year.

Karen Card seconds the motion of continual approval contingent upon reviewing Jamie Arango's completed forms assuming they are in agreeance with motion recommendation.

Total votes for approval: (Total members voting:) Affirmative: 4 Negative: 0 Recusal: 0 Absent: 0

Protocol Title: Sanofi YF-Vax Yellow fever vaccine in Florida.

Description: Dr. Ichite primary reviewer: This study has been ongoing and involves inviting subjects to take part in an extended axis program. Sanofi provides an investigational drug that is not yet approved in the US but in several other countries. No withdrawals from enrollment that we know of since the last review. Patients have been accrued over the study and there are no new risks or findings as a result of this study. No new safety monitoring reports submitted for continual review. All elements of informed consent are in place and he recommends to approve the submission for the next 12 months.

Jamie Forrest was the second reviewer: She agrees with Dr. Ichite and found it interesting to see the history of the study and this drug and the lack of availability of this drug over the last several years. She mentioned that this is really the only option for people to have access to this vaccine, so it makes sense for this experiment to continue.

Motion: Dr. Ichite motion to approve the continuation of the study for the next 12 months. Second: Jamie Forrest

The Committee provided rationale for the basis of IRB approval under 45 CFR 46.111 and 21 CFR 56.111 approve the study for another 12 months:

(1) Reviewers determined that this study is **not greater than minimal risk** and is consistent with sound research design and does not unnecessarily expose subjects to risk.

(2) Risks are reasonable in relation to anticipated benefits.

(3) Selection of subjects is equitable.

There are no vulnerable populations associated with this study.

(4) The Investigator has chosen a waiver of informed consent, which is appropriate for this study.

(8) Safeguards are in place for the rights and welfare of vulnerable populations.

No vulnerable populations in this study.

Letter:

Motion: Contingent Approval continuing review as **not greater than minimal risk** for 12 months and the study will work toward termination.

Total votes for approval: (Total members voting:) Affirmative: 4 Negative: 0 Recusal: 0 Absent: 0

Other business:

Bonnie: Four new applications for review to join the IRB committees.

Meeting Adjourned.