

June 7, 2017
9:00-10:30 AM



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

IRB 2 Convened Committee Meeting Minutes

IRB Attendance:

Jamie Forrest (Co-chair) (present by phone)

Nkechi Ichite (present by phone)

Kevin Sherin (present by phone)

Dongming Cui

Kelli Wells (present by phone)

Shamarial Roberson (Expertise in Subpart D: Children; Subpart B: Pregnant women)

Julie Moore (non-affiliated) (present by phone)

Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent)

Absent:

Carina Blackmore (Chair)

Jaime Arango (non-affiliated; person whose primary interest is non-scientific; present by phone)

Other Attendees: Rotanya Bryan, MPA, Dinithia Sampson, PhD, and Bonnie Gaughan-Bailey, MPA

Quorum

A quorum was present. *Katisa Donaldson is a member of the other board but attending this meeting because she has expertise in children and adults unable to give consent. In addition, her primary interest is non-scientific.

Approval of Previous Minutes:

Minutes from the **February 01, 2017** meeting were circulated by email and modified by member input.

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:

Education did not occur.

(#1) Protocol Title: Use of Stamaril Vaccine for Yellow Fever Immunization in Florida (Lee County)

Submission:

(Initial)

Principal Investigator:

Yvonne McConnell, MSN

Presenters:

Kelli Wells

Katisha Donaldson

Study Overview: Yellow fever is caused by the bite of an infected mosquito. Yellow fever is found in parts of Africa and South America. This is a new expanded access IND program to provide Stamaril vaccine to persons in the United States for vaccination against Yellow fever. Currently, Sanofi (Stamaril drug sponsor) has stopped production of the old Yellow fever immunization and has obtained an IND to fill in the gap. The treatment protocol will be conducted at the Florida Department of Health - Lee County. The plan is to provide the vaccination to those who request it.

Dr. Wells and Dr. Cui determined that risks are reasonable in relation to anticipated benefits and are the same as the old vaccination. Dr. Wells determined that the vaccination is less than minimal risk because it has been proven effective for over 20 years. Stamaril vaccine has the same efficacy as the old vaccine. The IRB determined that the design of the study is consistent with scientific standards. The primary reviewer also noted that there are potential risks for breastfeed mother transferring the vaccine to their nursing infant.

Dr. Wells determined that the selection of subjects is equitable because subjects are selected based on inclusion criteria which is based on an age range of 9 months to 60 years. There may be adverse events in those immunocompromised. Adverse events will be tracked through the protocol.

The researcher has chosen a long form written consent, which is appropriate for this study. The consent document includes all required disclosures, including whom to contact at the Department for additional information. No evidence of coercion in the consent form. Katisa Donaldson felt the consent form was sufficiently detailed. Parent and assent form for minors are adequate.

Committee members discussed the safety monitoring plan in the application and determined that adequate provisions were made for safety monitoring. No traditional follow-up. Standard monitoring on site for 20 minutes to observe for adverse events. Committee members noted that there will be no follow-up.

Children

Category 405: The research is greater than minimal risk for children under 9 months of age. There is the prospect of direct benefit to the children because the vaccine has been proven effective in providing immunization for Yellow fever. The primary reviewer noted that risks to children are less than that of contracting Yellow fever.

Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child, because there is a direct benefit to the child that could not be obtained outside the IND process.

Meeting Discussion: Jamie Forrest asked whether there were clean versions of the consent form. Rotanya Bryan informed her she would be sending out PDF versions of the clean (English) ICF. Dr. Sherin asked about the Spanish version of the consent form. Rotanya informed them that Spanish and Creole versions of the consent form were sent back to the translation company because they needed improvement. Dr. Wells suggested that the board table the study until the Spanish and Creole versions were approved. Dr. Roberson noted that local departments have State Translation Line and may be able to use that to fill in the gap. Julie Moore suggested that the board approve the consent form and then allow the researchers to send in the Spanish and Creole versions as a modification, to be approved using expedited procedures.

Motion: A motion was made and seconded.

Total votes to approve for 12 months: Affirmative:8 Negative:0 Recusal:0 Absent:2

(#1) Protocol Title: Use of Stamaril Vaccine for Yellow Fever Immunization in Florida (Miami/Dade)

Submission:
(Initial)

Principal Investigator:
Jorge Alonso

Presenters:
Kelli Wells
Doming Cui

Study Overview: Yellow fever is caused by the bite of an infected mosquito. Yellow fever is found in parts of Africa and South America. This is a new expanded access IND program to provide Stamaril vaccine to persons in the United States for vaccination against Yellow fever. Currently, Sanofi (Stamaril drug sponsor) has stopped production of the old Yellow fever immunization and has obtained an IND to fill in the gap. The treatment protocol will be conducted at the Florida Department of Health – Miami-Dade County. The plan is to provide the vaccination to those who request it.

Dr. Wells and Dr. Cui determined that risks are reasonable in relation to anticipated benefits and are the same as the old vaccination. Dr. Wells determined that the vaccination is less than minimal risk because it has been proven effective for over 20 years. Stamaril vaccine has the same efficacy as the old vaccine. The IRB determined that the design of the study is consistent with scientific standards. The primary reviewer also noted that there are potential risks for breastfeed mother transferring the vaccine to their nursing infant.

Dr. Wells determined that the selection of subjects is equitable because subjects are selected based on inclusion criteria which is based on an age range of 9 months to 60 years. There may be adverse events in those immunocompromised. Adverse events will be tracked through the protocol.

The researcher has chosen a long form written consent, which is appropriate for this study. The consent document includes all required disclosures, including whom to contact at the Department for additional information. No evidence of coercion in the consent form. Katisa Donaldson felt the consent form was sufficiently detailed. Parent and assent form for minors are adequate.

Committee members discussed the safety monitoring plan in the application and determined that adequate provisions were made for safety monitoring. No traditional follow-up. Standard monitoring on site for 20 minutes to observe for adverse events. Committee members noted that there will be no follow-up.

Children

Category 405: The research is greater than minimal risk for children under 9 months of age. There is the prospect of direct benefit to the children because the vaccine has been proven effective in providing immunization for Yellow fever. The primary reviewer noted that risks to children are less than that of contracting Yellow fever.

Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child, because there is a direct benefit to the child that could not be obtained outside the IND process.

Meeting Discussion: Jamie Forrest asked whether there were clean versions of the consent form. Rotanya Bryan informed her she would be sending out PDF versions of the clean (English) ICF. Dr. Sherin asked about the Spanish version of the consent form. Rotanya informed them that Spanish and Creole versions of the consent form were sent back to the translation company because they needed improvement. Dr. Wells suggested that the board table the study until the Spanish and Creole versions were approved. Dr. Roberson noted that local departments have State Translation Line and may be able to use that to fill in the gap. Julie Moore suggested that the board approve the consent form and then allow the researchers to send in the Spanish and Creole versions as a modification, to be approved using expedited procedures.

Motion: A motion was made and seconded.

Total votes to approve for 12 months: Affirmative:8 Negative:0 Recusal:0 Absent:2

Next Meeting: July 5, 2017

Other Business: Rotanya Bryan informed board members that there is a meeting on June 12, 2017 to revise the Common Rule revisions.

Meeting Adjourned: 9:50am