

August 5, 2015
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:

Carina Blackmore (Chair)
Jaime Arango (non-affiliated; person whose primary interest is non-scientific; present by phone)
Daniela Chiriboga Salazar
Jamie Forrest
Cheryl Clark (Expertise in children, pregnant women)
Nkechi Ichite (present by phone)
Nina McGrew (absent)
Daniel Thompson (expertise in children, pregnant women)
Brenda Whittenberg (Expertise in Subpart C: Prisoners, non-affiliated; present by phone)

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 July 1, 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:

Dr. Chiriboga presented the educational materials today on the current and past state of HIV medications. An overview of the four primary classes of HIV medications was reviewed (integrase inhibitors, protease inhibitors, fusion inhibitors, and RT inhibitors). Drugs in each of the main four categories currently in clinical trials were presented. Common treatment regimens for treatment naïve adults, children, pregnant women, and treatment experienced adults was provided. Contraindicated medications between the main classes of medications were listed.

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

Submission:

Initial Review

Principal Investigator:

Walter Bradley DM, FRCP

Presenters:

Carina Blackmore
Dan Thompson

Meeting Discussion:

This is a new study looking at incidence of ALS in Florida using the Florida ALS Surveillance Database. ALS patients' information was entered into a CDC-funded database between 2009 through 2011 to test the feasibility of developing a national ALS database. Florida has a history of algal cyanobacterial blooms, some causing acute animal deaths and human illness, some causing chronic illness. The purpose of this study is to examine the effect of environmental toxins, specifically BMAA on ALS incidence using geomapping of patients' addresses. The researcher proposes to protect confidentiality through the use of a dithering technique to obscure the addresses. Specific environmental toxins the study plans to examine are: Superfund and Brownfield site, landfills, commercial and municipal incinerators, and aerosolized excretions from cyanobacteria in waterbodies.

IRB members were unable to determine the criteria for approval were met and a motion was made to request additional information, which is listed below. The motion was approved by 8 members. One member was absent from the meeting.

Additional information requested from the researcher:

- Describe plans to address limitations due to multiple comparisons or multiple tests of significance when each of many geographic areas are tested for significantly high statistics. Include a plan to create a 2 x 2 table of cases and controls by exposure status (exposed and not exposed) for the statewide data set, and describe how this table will be used to obtain statewide odds ratios with confidence intervals.
- Describe a plan for community engagement to ensure stakeholders understand what the results of the research mean. Identify stakeholders; describe the method for engagement; and describe the information to be provided and process to ensure understanding. Examples of methods of community engagement include the use of community advisory boards, holding meetings (in person or virtually, for example, using skype or other conference call system), and meeting individually with community leaders or leadership of stakeholder organizations. Examples of information to be provided: an overview of research, designed for the general public, a background on the research problem, and a description of what the results of the current project mean, and what the results do not mean, and what needs to happen next in terms of additional research.
- Describe the impacts on the design if the initial release of data were limited to areas where there was high quality environmental data about algae and toxin release - including but not limited to the St. Johns River Water Management District and have the results from this study guide further data release. Since different species of algae present different environmental toxin exposures, which may or may not be produced and released during blooms, describe whether remote sensing can provide the same quality of data as direct measures of algae with species classification and toxin testing.

Next Meeting: September 2, 2015

Other Business: None

Meeting Adjourned: 10:27 am

