

October 19, 2016
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:

Bob Eadie (non-scientist)
Daphne Holden
Nina McGrew (non-affiliated)
Keshia Reid (Expertise in Subpart B: Pregnant women)
Karen Card

Absent:

Katisa Donaldson (non-affiliated) (non-scientist)
Sandra Schoenfisch (Chair, Expertise in Subpart D: Children) (non-affiliated)
Ovidiu Cotea (Present by phone)

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

Quorum

A quorum was present. A quorum is defined as the majority of the IRB members and representation of each of the members as identified in the requirements outlined in 45 CFR 46.108 as well as 21 CFR 56.107. 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 **September 21, 2016** 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: Recruitment Considerations and Justice

Karen Card reviewed major points IRB members must consider when assessing the equity of research among populations. One such point is that individual justice requires fairness in participant selection. Even where a researcher uses a fair selection method, injustice might result that arises from social, racial, sexual, and cultural biases institutionalized in society; unjust social patterns may appear in the overall distribution of burdens and benefits of research. Researchers can consider distributive justice in recruiting research subjects.

Another point was that vulnerable or incapable populations should not be exploited. Even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

Initial review

(1) Protocol Title: Biobank for African American Prostate Cancer Research in Florida

Submission:
(Initial Review)

Principal Investigator:
Jong Park, PhD

Presenters:
Keshia Reid
Nina McGrew

Meeting Discussion: Researchers at Moffitt seek to create a biobank of previously collected African American men cancer tissue samples and determine whether smoking causes the aggressiveness of prostate cancer. This study is a previously reviewed project and was tabled out of concerns that the consent form, privacy protections, and standard operating procedures were inadequate. Keshia Reid requested that researchers provide procedures for managing a bio specimen bank. HRPP staff reached out to the researchers for revisions. Keshia and Nina found the revisions to be acceptable. Nina McGrew made the observation that the protocol should have been split into two separate protocols. One protocol would have addressed the creation of the biobank and the second protocol would have answered the hypothesis put forward.

Nina also noted that the consent form should have been separate documents that addressed the biobank and the hypothesis separately. Daphne raised some concerns about the length of the ICF. Both reviewers found the ICF to be lengthy, but it provided adequate protections for participants. Karen brought up whether or not it was advisable to keep this study on the convened agenda. Members came to the conclusion that the study would be kept as a convened study for one more year and then the committee would reevaluate the study.

Motion: A motion of approval for one year was made and seconded.

Total votes for approval: Affirmative: 5 Negative: 0 Recusal: 0 Absent: 3

Next Meeting: November 16, 2016

Other Business: HRPP staff provided updates on the new online system and Bonnie announced the Public Health Research's \$25 million Zika funding allocation.

Meeting Adjourned: 2:00 pm