

IRB Meeting Minutes
Bioscience Committee
5/17/2017

MEETING TIME RECORDS

Meeting start time: 12pm
Meeting end time: 12:50pm

VOTING MEMBER ATTENDANCE

Name of Regular/Alternate Member	Status	Substituting For	Present by Teleconference?
Antony Denton	Present		
Allan Markus	Absent		
Christopher Stojanowski	Absent		
Ginger Hook	Present		
Elizabeth Reifsnider			Present
Carol Johnston	Present		
Douglas Lake	Present		
Donna Pearcy	Present		
Shad Marvasti	Present		

QUORUM INFORMATION

Number of IRB members on the roster: 9
Number required for quorum: 5

All members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

ATTENDANCE STATUS AND VOTING KEY

ABSTAIN:	Present for the vote, but not voting "For" or "Against."
ABSENT:	Absent for discussion and voting for reasons other than a conflicting interest.
RECUSED:	Absent from the meeting during discussion and voting because of a conflicting interest.
SUBSTITUTION:	When regular members and their alternate(s) are listed in the ATTENDANCE table above and an alternate member substitutes for the regulator member this identifies the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions.

GUEST NAMES

Susan Metosky
Erik Williams
Debra Murphy

GENERAL MEETING INFORMATION

1. Carol Johnston called for conflict of interests of the members. There were none reported.
2. The next item on the agenda was the review of the minutes from the previous meetings. A motion was made to accept the minutes of the March 15, 2017 IRB meeting with one minor change to a typo. The committee voted to approve the minutes by a vote of 5– Yes, 0 – No, 2– Abstain.
3. Educational materials were distributed at the meeting.
4. The review of studies approved through expedited review was available through ERA IRB.

REVIEW OF STUDIES

1. Review of CR00003018:

Type of Review:	Continuing Review
Title of Study:	Continuing Review for Study 1206007979
Investigator:	Rosa Krajmalnik-Brown
IRB ID:	CR00003018
Funding:	None

a. **Additional information and notes:**

The study examines types and amount of bacteria in stools of individuals with and without autism, (4 populations are recruited: autistic with major gastrointestinal issues, autistic with minor gastrointestinal issues, non-autistic with major gastrointestinal issues and non-autistic with minor gastrointestinal issues.)The study is funded by a gift to ASU from the Bhare Foundation. The researchers proposed to enroll 70 participants ages 3-17. At the last review, researchers had enrolled a total of 17 participants (8 autistic and 9 controls). No new participants were enrolled this review period, researchers focused on data analysis. Discussion included the assent process for autistic children.

b. **Recommended changes and reasons:**

None

c. **Determinations and findings that require documentation:**

The IRB determined that the study meets the criteria under 45CFR46.404 for research not involving greater than minimal risk to minors with parental permission and child assent. The committee also voted to defer review of this study to expedited review.

d. **Motion: Approve**e. **Votes: 7**

For:	7
Against:	0
Abstain:	0
Absent:	2
Recused:	0
Substitutions:	0

2. Review of CR00003002:

Type of Review:	Continuing Review
Title of Study:	Continuing Review for Study STUDY00001286
Investigator:	Sonia Vega Lopez
IRB ID:	CR00003002
Funding:	Name: American Heart Association, National Center, Funding Source ID: 14SDG20490382

a. **Additional information and notes:**

The purpose of this project, funded by the American Heart Association, is to test the effectiveness of a child physical activity and nutrition program, "Athletes for Life", delivered in a local City Recreation Center. This study is a twelve week program for adults and children. Study procedures include blood draws, DEXA measurements, fitness testing and activity monitoring.

b. **Recommended changes and reasons:**

None

c. **Determinations and findings that require documentation:**

The IRB determined that the research was permissible under 45CFR46.405 for research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects with parental permission and child assent.

d. **Motion:** Approve

a. **Votes:** 7

For:	7
Against:	0
Abstain:	0
Absent:	2
Recused:	0
Substitutions:	0

The committee discussed changes to Federal Regulations 45CFR46. Debra asked the members to review the changes that will become effective in early 2017 to provide their input on implementation recommendations. Carol Johnston, chair of the committee and most experienced expedited member reviewer will draft guidelines for review of studies meeting expedited review criteria that she recommends will require continuing review. The topic will be included on the agenda for discussion at an upcoming IRB meeting.

The IRB also discussed a study in which participants would have to pay to be part of the study. The IRB questioned the voluntary nature of the study.