1. Abstract:

This purpose of this research study is to see if children learn how to make healthy decisions regarding their diet and physical activity as a result of participating in the Up for the Challenge (UFC) program, as measured by the evaluation surveys. The Up for the Challenge: Lifetime Fitness Healthy Decisions curriculum is a fitness, nutrition and health curriculum designed for school-aged, middle school and teen youth. It is used in after-school and in-school 4-H settings including 4-H clubs, military child care facilities and various youth-serving organizations. The curriculum is divided into five chapters with each chapter containing multiple lessons in physical activity, nutrition and healthy decision making. Lessons range in scope and length from 30-60 minute nutrition and/or physical activities to a multi-week wellness event.

This project will determine if UFC is improving healthy behaviors in youth including increased consumption of fruits and vegetables and increased physical activity as measured by these surveys.

There are no known risks or discomforts associated with this research outside of the normal physical discomfort associated with normal physical activities. All participants are enrolled in the Maryland 4-H program. The 4-H program is the world-wide youth development program for children of military families.

2. Subject Selection:

a. Recruitment: Youth participating in this study are enrollees of existing 4-H clubs, school or military after-school day groups or other after-school care facilities such as Parks and Recreation programs that serve elementary and middle-school children and where 4-H educators have established the 4-H program. Youth ages range from 8-14.

b. Eligibility: All youth in the schools and after-school 4-H programs are eligible to participate. Participating schools may be in any of the 23 counties and City of Baltimore in that UME programs are offered throughout the State of Maryland.

c. Rationale: The program is based on materials developed for youth and their needs for physical fitness and a healthy lifestyle.

d. Enrollment Numbers: Estimate of the total number of participants is 250.
3. Procedures:

Prior to the start of the program, parents with children in the participating schools will receive a letter from the PI letting them know about the program and the research, the purpose of the research, that there are no known risks or discomforts associated with the research, that participation is voluntary, that no identifying information will be kept about their child, and that the data will be kept in a secure location. They will also be told about the types of questions their children will be asked. Parents who do not want their children to participate in the research will be requested to return a signed form or contact the teacher or the PI. If a parent does not want the child to participate in the research, the child may participate in the educational program. Those children not completing the assessment will simply be asked to remain in their seats for the few minutes it will take the other children to complete the survey assessment and will be given other activities to do during the jump rope test. In this way, those children not participating in the research will not be made obvious and those children completing the assessment will not be disturbed or interrupted by the other children leaving.

The UFC curriculum is made up of six lessons. If children participate in at least six lessons, they will complete a pre-test before the first lesson and a post-test at the conclusion of the last lesson. They will also participate in a three minute jump rope test at the beginning of the first lesson and the end of the last lesson. The jump rope assessment will be coordinated by UME staff. Children will be broken into groups of two and given instructions for one child to jump while the second child counts the number of completed jumps during a three-minute period. Children not participating will be given the option of playing games while the assessment is taking place. If children complete fewer than six lessons, they will complete the Day in the Life survey at the beginning of their first lesson and the end of their last lesson. The number of lessons completed by each student will be tracked by sign-in sheets on the day the lessons are given.

Surveys will be administered by teachers or UME staff members. Before the pre-assessment begins, teachers will read the assent information to the students. Students will be told what the research is about, how it will be conducted, how long it will take (10 minutes or less), that there are not any risks to participating, that they may choose to not participate and still remain in the 4-H group/club, that their information will only be known by the researcher and will not be told to anybody else, and that if they do not want to participate, they should tell the teacher. Personal identifying information collected from the youth includes names, age and gender. Surveys can be administered orally if literacy is an issue. Surveys will not be administered to children younger than 8 years old. If the student chooses not to participate, the teacher will simply record the name of that student for the PI on the form. The same assent information will be read to the students at the before administering the post-assessment.
4. **Risks:**

There are no known risks or discomforts associated with this research outside of the normal physical discomfort associated with jumping rope or doing other normal physical activities such as dancing and walking.

5. **Benefits:**

There are no direct benefits to participants but some possible benefits include that the information gained in this study will help researchers develop effective intervention programs for children related to adopting behaviors associated with a healthy diet and increased physical activity.

6. **Confidentiality:**

No identifying information will be kept about participants and all of their answers will remain confidential. Information will be analyzed but not matched with names. The data will be stored in a locked cabinet at the offices of Principal Investigator in the Montgomery County Extension office and will only be seen by the investigator during the study and for three years after the study is complete. All data will be destroyed at the end of the three years.
7. Consent Process:

A letter describing the survey will be sent home to parents with an attached form on which parents can indicate if they do not want their child participating in the survey or jump rope test. We are applying for a waiver of parental consent for those not returning their forms since the survey and jump rope test involve no more risk than what youth would normally be exposed to during a school day or at a camp or club since jumping rope is similar to other activities conducted in these venues (such as outdoor games or dancing) and a pencil survey is similar to a short school quiz. This waiver would not affect the rights of the subjects as youth are allowed to opt out without repercussion if they choose not to participate. It would be difficult to conduct the pre-survey at the beginning of the program if we waited for youth to return signed forms as they can be repeatedly lost or forgotten.

Before the pre-assessment begins, teachers will read the child assent information to the students. Students will be told what the research is about, how it will be conducted, how long it will take (10 minutes or less), that there are not any risks to participating, that they may choose to not participate and still remain in the 4-H group/club, that their information will only be known by the researcher and will not be told to anybody else, and that if they do not want to participate, they should tell the teacher. If the student chooses to not participate, the teacher will simply record the name of that student for the PI on the form. The same assent information will be read to the students before administering the post-assessment.

8. Conflict of Interest:

No conflict of interest.

9. HIPAA Compliance:

Not applicable.

10. Research Outside of the United States:
11. Research Involving Prisoners:

Not applicable.

12. SUPPORTING DOCUMENTS

Your Initial Application must include a completed Initial Application Part 1 (On-Line Document), the information required in items 1-11 above, and all relevant supporting documents including: consent forms, letters sent to recruit participants, questionnaires completed by participants, and any other material that will be presented, viewed or read to human subject participants.

For funded research, a copy of the Awarded Grant Application (minus the budgetary information) must be uploaded. If the Grant has not been awarded at the time of submission of this Initial Application, a statement must be added to the Abstract Section stating that an Addendum will be submitted to include the Grant Application once it has been awarded.

THE IRB OFFICE WILL NO LONGER STAMP CONSENT FORMS. THE CONSENT FORMS IN YOUR APPROVED IRBNET PACKET MUST BE USED. THESE ARE YOUR APPROVED CONSENT FORMS.