



LOMA LINDA UNIVERSITY

School of Public Health



PhysicalGenesis Parent Consent Form

We are happy to inform you that you and your child are invited to participate in the **PhysicalGenesis Study for children and adolescents that attend 5th to 11th Grade** in any of the participating schools in the North American Division of Seventh-day Adventists (NAD). Have you ever wondered if physical fitness is related to school performance and how what you eat and do can influence your health? How can we prevent obesity in children and improve the health and happiness of our children? Questions like these are of great interest for parents, teachers, and researchers. To find answers to these questions we need your help. The study is designed by experienced researchers from Loma Linda University and La Sierra University and has been approved by the NAD to be conducted in all Seventh-day Adventist schools.

How will the study be conducted?

When you allow your child to participate, you and your child will be asked to complete independently an online survey. The survey will include questions about dietary habits, sport and leisure time activities and other questions that will help us to understand better how health habits can be related to fitness, health, and academic performance. The survey may take between 30 to 50 minutes. **All the collected information will be handled with the highest confidentiality. None of the teachers, school administrators, or other third parties will have access to your personal data.** Only unidentifiable summary reports of study results will be provided to the NAD Office of Education. All children will participate in a fitness test that will be integrated in the activities of the school and administered by their teacher. Physical fitness will be assessed using the FitnessGram tool (<http://www.fitnessgram.net>). FitnessGram is a comprehensive, educational, reporting and promotional tool used to assess physical fitness and physical activity levels for children. It was first developed in 1982 by the Cooper Institute and is the most widely used children's health-related physical fitness assessment in the world. The tests include shoulder stretch, trunk lift, curl up, push up, and a simple aerobic fitness test. In addition, height and weight will be measured. Participation in the health survey and the fitness tests are voluntary and can be stopped at any time by you and your child. We plan to repeat the survey and the fitness tests every year for the next five years to find out how health habits and fitness may change over time.

Are there any other investigations that the children may participate in?

Some of the children may be invited by the investigators to participate in additional sub-studies that will help us find out if we measured and assessed the children correctly. Those who want to participate in these studies will repeat the physical fitness tests, answer detailed questions about the foods eaten over a certain time period (six times over a three month period), and be given small activity monitors (similar in size to pedometers). This will help us to see how active the children are during the day and how the self-reported answers relate to the measured physical activity. As part of these sub-studies your child may be invited to blow air into a tube for airflow testing. The test procedure is similar to blowing out a birthday candle. Your child may also be asked to funnel saliva through a straw into a collection tube that will be used to test for inflammation and stress markers.

Other sub-studies may be conducted that may require additional assessments. Students and parents that are invited for those studies will be thoroughly informed about the content of those studies and be provided with a separate consent form if they choose to participate.

The participation in any of the sub-studies is entirely optional and voluntary, can be withdrawn at any time, and does not affect the participation in the main study.

Will it hurt?

Participating in the study will cause no pain. The fitness tests will be supervised by a teacher. Only students that have passed a Physical Activity Readiness Questionnaire may take the physical fitness test. Students who cannot participate in the physical fitness test can still participate in the questionnaire based health behavior survey.

Will I benefit from participating in the study?

All children that participate will find out their physical fitness levels. They will learn how to interpret those results and how their fitness can be improved. In addition all who participate will get a first hand experience in a research project. Your contribution can help to improve the health and fitness of students and improve the school environment.

Participant's Rights and Security

Participation in the PhysicalGenesis Study and its sub-studies is voluntary. You and your child are free to withdraw at any time, for any reason without penalty. If you are invited to participate in any of the sub-studies you may choose to participate or not. Your choice will not affect the ability to participate in the main study. **All the collected information will be handled with the highest confidentiality, and none of the teachers, school administrators, or other third parties will have access to your personal data.** The web based survey is designed to meet both the Health Insurance Portability Accountability Act (HIPAA) and Family Educational Rights and Privacy Act (FERPA) standards. Identifiable data will only be accessible to the principal investigators. Only unidentifiable data will be made available to approved researchers. Summary reports of collective study results that cannot be identified will be made public and reported to the Office of Education at the NAD.

What if I want to know more about the study?

Should you have any questions about the study you can check first with your child's teacher. You can read the materials that are provided at the website (www.PhysicalGenesis.com) and watch the videos that explain why we are conducting the study and how it is being done. For further questions, you may also contact the primary investigators; Dr. Nico S. Rizzo and Dr. Robert K. Thomas. For specific questions in regards to the physical fitness tests please contact Dr. Robert K. Thomas at the Health & Exercise Science Department, La Sierra University, 4500 Riverwalk Pkwy, Riverside, CA 92515, email: PhysicalGenesis@LaSierra.edu. For questions in regards to the Health Behavior Survey and the sub-studies please contact Dr. Nico S. Rizzo at the Center of Community Resilience, School of Public Health, Loma Linda University, 24951 North Circle Drive, Loma Linda, CA 92350, email: PhysicalGenesis@llu.edu.

Third Party Contact

If you wish to contact an impartial third party not associated with this study regarding any complaint you may have about the study, you may contact Patient Relations, Loma Linda University Medical Center, Loma Linda, CA 92350, Phone 909-558-4647 or the Director of the Office of Sponsored Research at La Sierra University, Dr. In-Kyeong Kim at ikim@LaSierra.edu for information and assistance.

Informed Consent Statement

I have read the contents of this consent form and am informed about the study. I understand the commitment required of me and my child, as well as the potential risks and benefits. My questions concerning this study have been answered to my satisfaction. I hereby give voluntary consent for me and my child to participate in the PhysicalGenesis Study conducted by Loma Linda University and La Sierra University.

Please provide the following information in Capital Letters if you consent to participate and have your child participate in the Study:

My First Name: _____

My Last Name (Family Name): _____

My Email: _____

My Phone Number: _____

Yes, I and the child under my legal guardianship want to participate in the PhysicalGenesis Study. I hereby authorize a designated School Official to enter my consent online at www.focusedfitness.org

**Signature of Parent or
Legally Authorized Representative**

Date and Place

Please provide the following information in Capital Letters about your son, daughter or child under your legal guardianship who is participating in the study:

Student ID Number: _____

First Name: _____

Last Name (Family Name): _____

Male: or Female:

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