UNIVERSITY OF THE WITWATERSRAND

SCHOOL OF PHYSIOLOGY

INFORMATION SHEET

Influence of Weight-Bearing Activity on Bone Density

Hello, my name is Rebecca Meiring. My co-investigators, Dr Ingrid Avidon and Dr Joanne McVeigh and I work in the exercise laboratory at Wits Medical School. We are conducting research in the field of exercise and bone density (bone health). We are interested in the effects of exercise on the bone health of South African children.

Children gain most of their bone mass before they reach puberty. High impact sports such as football, running and netball have beneficial strengthening and building effects on the bones of the body. We would like to find out what effect previous and current participation in high and low impact sports has on the development of the bone mass in children just before they reach puberty (ages of 8 to 11 years).

We would appreciate it if you would assist us with our research by allowing your child to participate in our research project. If you agree, and your child is willing to participate, you will be asked to visit the Exercise Laboratory, at your convenience, which is located at the Wits Medical School Campus in Parktown, Johannesburg on **three** separate occasions over the course of a year. For all of the visits, we will pay for your and your child's travel expenses to and from the Laboratory.

Visit 1 to Exercise Laboratory

When you bring your child into the Exercise Laboratory, you will be asked to help them fill out some questionnaires. You are welcome to look at these questionnaires in advance. The principal investigator (Rebecca) will help you complete these questionnaires if needed. The first questionnaire is a general health questionnaire which informs us of your child's general health. The second questionnaire is a seven day dietary recall questionnaire which asks questions about your

child's diet and calcium intake for seven days. The third questionnaire is a physical activity questionnaire which asks questions about your child's current level of physical activity and their level of physical activity in the previous two years. In order to ensure the visit is as quick as possible, the 2nd and 3rd questionnaires can be taken home with you and filled out at your leisure and can be collected at an alternative time. The fourth questionnaire will need to be filled out at the lab by your child with your help. This pictorial questionnaire is a self-assessment of their sexual maturity and is needed to determine their stage of puberty. It will take approximately 30 minutes to complete all the questionnaires. During the visit to the laboratory we would also like to perform a bone scan on your child. This scan takes about 30 minutes to complete and your child will need to lie still while he/she is being scanned. The scan emits an extremely low level of radiation (less than that of a dentists x-ray) making it safe for children and even safe for pregnant women. This scan will give us a lot of information about your child's bone and body composition. If your child is willing, we would also like to take a small blood sample from a vein in their arm. A nurse will use a needle to draw 10 millilitres (about 2 tablespoons) of blood from their arm. To take away the pain your child might experience from the needle, an anaesthetic cream can be applied to the arm area before the blood is collected. Your child may decide whether or not he/she wishes to give blood. At some stage during the visit, when your child needs the toilet, we would like your child to provide a urine sample (about half a cup). The blood and urine will be used to test for markers that give us information about the health of your child's bones. The blood will be tested for substances that give us an indication of bone being formed. Specifically the substances are hydroxyproline, osteocalcin and alkaline phosphatase. The urine sample will allow us to look for a substance that shows bone being broken down. The first visit to the lab should last about two hours. You and your child are free to end participation in the study at this point, however a follow up option is available and is described below.

If you agree to your child's continued participation, and your child is willing, we would like to invite you to continue in our research project for a further 12 months. During these 12 months your child will be asked to continue their normal physical activities and activities of daily living. Please note that your child will not need to change their routine or diet in any way during this year but continue in their normal activities as before. They are allowed to begin new sports and activities if they wish. During this time you would be required to visit the Exercise Laboratory for two more visits that are spaced six months apart.

<u>Visit 2 (after six months)</u>

After six months your child will need to visit the Laboratory for a blood test, urine test and bone scan, as described in the first visit. In addition, we will require you to complete a physical activity

questionnaire and dietary recall questionnaire as described in visit 1. This visit will take approximately one hour. Seven days before this visit, we would like your child to wear a small activity data logger on their hip. This logger is a square plastic cube about the size of a bottle top and is light and unobtrusive. The logger is fitted on a belt and worn under the clothing. The logger monitors the level of activity of your child during the day by measuring movement. The logger needs to be taken off when your child baths, showers or swims. It can also be removed when your child goes to sleep at night and then put on again in the morning. We would require your child to wear the logger for one full week (seven days). When the week is over the logger can be dropped off at the lab when your child comes in for their six month visit.

Visit 3 (after 12 months)

After 12 months your child will need to visit the Laboratory for a blood test, urine test and bone scan, as described in the first visit. In addition, we will require you to complete a physical activity questionnaire and dietary recall questionnaire as described in visit 1. This visit will take approximately one hour. Seven days before this visit, we would like your child to wear a small activity data logger on their hip as described above. When the week is over the logger can be dropped off at the lab when your child comes in for their 12 month visit.

In summary, the flow chart below describes the order of measurements and visits:

Visit 1 (approximately 2 hours)

- Four questionnaires
- Bone scan
- Blood and urine test

Visit 2 – 6 months after visit 1 (approximately one hour)

7 days before visit wear logger for 7 days

- Physical activity and dietary questionnaire
- Bone scan
- Blood and urine test

Visit 3 - 12 months after visit 1 (approximately one hour)

7 days before visit wear logger for 7 days

- Physical activity and dietary questionnaire
- Bone scan
- Blood and urine test

Please note that transport to the University from your child's school and back, can be arranged for your child. This has been discussed and will be arranged accordingly with the head of the school and yourself.

Your child's participation in the study is voluntary and **you will be able to withdraw your child's participation at any stage during the study without any prejudice to yourself or your child.** I would like to stress that giving blood is completely optional and if your child chooses not to give blood he/she is still eligible for the study including the 6 month and 12 month follow up visits. All the results will be kept confidential and will be made available only to the researchers involved in the study and yourself. If you wish, we will discuss your child's results with you so that you can gain information on their bone health and how to improve or maintain their bone strength. All records of your child's results will be identified by a reference number, so that he/she remains anonymous. All the data from the study will be put together, analysed and the results published in research papers written for the scientific community. We have obtained approval for the study from the Committee for Research on Human Subjects of the University of the Witwatersrand (ethics clearance number: M10635). If you have further questions please do not hesitate to ask me or one of my co-investigators.

Thank you for considering your child's participation in this study. Please read the information sheet carefully*. Should you be interested in allowing your child to participate in this research, please contact Rebecca to discuss further involvement:

Cell: 076 311 2725 (send SMS with your name and I will call you back)

Tel: 011 717 2358

Email: Rebecca.Meiring@wits.ac.za

Fax: 011 643 2765 or 086 671 6118

Sincerely,

Rebecca Meiring

*If you have any doubts to your rights as a subject please feel free to contact **Anisa Keshav**, Wits Research Office, 10th Floor Senate House, East Campus.

Tel: 011-717-1234 Fax: 011-717-1265 Email anisa.keshav@wits.ac.za