VITamin D for AdoLescents with HIV to reduce musculoskeletal morbidity and ImmunopaThologY: VITALITY Study

Principal Investigator: Rashida Ferrand [MBBS, FRCP, PhD]
Phone: [Telephone number]

What you should know about this research study

PURPOSE
You are taking part in the VITALITY study. We would like to measure how easily participants are able to take their study medication in this study. We are asking 100 children who take part in VITALITY selected by chance to use an electronic pill dispenser called Wisepill RT2000 dispenser which is used to keep your tablets. The dispenser records the date and time every time that it is opened.

PROCEDURES AND DURATION
We will teach you how to use the Wisepill RT2000 dispenser. The study team will put your vitamin D tablets in the electronic pill dispenser. We will ask you to open the electronic pill dispenser only when you have to take your vitamin D tablets and ensure that it is closed after use. We will ask you to use the electronic pill dispenser for 24 weeks, after which you should return the electronic pill dispenser to the study team. We will ask you to come to the clinic after two weeks to check if you have had any problems with using the electronic pill dispenser.

RISKS AND DISCOMFORTS
There are no risks or discomfort associated with participating in the study.

BENEFITS AND/OR COMPENSATION
We cannot guarantee or promise that you will receive any benefits from this study, but the study may help other children in the future. Taking part in the study will not cost you anything and the electronic pill dispenser will be given free of charge. We will not pay you to use the dispenser.

CONFIDENTIALITY
If you indicate your willingness to participate in this study by signing this document, all information obtained will be stored anonymously in safe paper and computer files. Information collected from the electronic pill dispenser will be saved in a password protected computer. No one will be able to access the information about you except for the research team and no one will be able to identify you from the information we collect. This information may be shared with researchers in the future as it will be stored on an electronic database but can only be used in ethically approved studies.

VOLUNTARY PARTICIPATION
Participation in this study is voluntary. If you decide not to participate in this study and use the electronic pill dispenser, your decision will not affect your continued participation in the VITALITY study, future relations with this clinic, associated hospitals, and its personnel or with the institutions working on this study. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without penalty.

WHO TO CONTACT WITH QUESTIONS OR PROBLEMS
If you would like more information or have any questions about this study, please ask the study team or contact the Study Coordinator: Dr Nyasha Dzavakwa on Telephone number: 0773 659 363

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AUTHORIZATION

YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE IN THIS STUDY. YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTOOD THE INFORMATION PROVIDED, HAVE HAD ALL YOUR QUESTIONS ANSWERED, AND HAVE DECIDED TO PARTICIPATE.

Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over.

- I have read the information sheet concerning this study [or have understood the verbal explanation] and I understand what will be required of me and what will happen to me if I take part in it.
- I understand that at any time I may withdraw from this study without giving a reason and without affecting my normal care and management.

I agree to participate in this study YES ☐ NO ☐
I agree to use the Wisepill RT2000 dispenser YES ☐ NO ☐
I agree for study team to phone me in the future about studies that I may be eligible for YES ☐ NO ☐

Consent from participant:

Name of Participant (Print)	Signature of Participant	Date
Name of Research Staff (Print)	Signature of Research Staff	Date

If the participant gave verbal assent, name of person who witnessed the assent here, and signature:

Name of Witness (Print)	Signature of Witness	Date

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research subject or research-related injuries; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the research team, please feel free to contact the Medical Research Council of Zimbabwe on Telephone: 0242 791792 or 0242 791193. Cell: 0772 433 166