

GENERAL GUIDELINES AND SOP FOR USE OF SMARTPILL® DATA RECEIVER

You will be given a Data Receiver to be worn by you on a lanyard at all times during the study right from the ingestion of the SmartPill® (Capsule) until the day you pass it out.

- It is important that for accurate measurements you:
 - MUST be fasted for the required time mentioned on the information sheet before ingesting the capsule
 - MUST NOT be taking any medications that influence gastrointestinal transit or alter gastric pH (we will assess your eligibility when you come in for your screening session). If however you do start to take ANY MEDICATION thereafter you MUST notify us of the same.
- We will calibrate the capsule before you swallow it and ensure that the data receiver is receiving information from the capsule.
 - It is important for that you attend your session on the day scheduled. If you are UNABLE to come to the laboratory for any unforeseen reasons kindly contact us at the earliest. This is because once the SmartPill® has been calibrated and turned on we have to use it within a 2 hour window period.
- We will give you a *Card* that states your name and our details on it.
 - This *Card* must be carried by you at all times when you are on the Test. The purpose of this is to inform any person, in healthcare or otherwise that you have ingested the SmartPill. This is a precautionary measure as you cannot undergo a Magnetic Resonance Imaging (MRI) until confirmation of the passage of the Capsule.
- The Capsule normally passes naturally within 2-5 days. You will be required to visually confirm this and record it in the Diary given to you and mark it as an 'event' on your Receiver (see below).
- You will be contacted everyday that you are on the Test at a time convenient for you to ensure that you are not experiencing any discomfort.

IF at any time you experience any discomfort or have queries do not hesitate to contact Ivana Sequeira on the number provided in the Information Sheet and *Card*.

- Restrictions after capsule ingestion and during the test:
 - If the Capsule and the Receiver are separated by more than five feet data will be lost. Therefore, ensure that you keep the Data Receiver on the body whenever possible throughout the test.

- DO NOT wear the Receiver while bathing or showering, keep the receiver dry and as close to the body as possible.
- You must wear the Receiver suspended by the lanyard and kept as close to the abdominal area as possible.
- However, do not use the lanyard while sleeping. Ensure that the receiver is kept close to you when you are in bed.
- Recording an 'Event':
 - To place a marker in the electronic record you must depress the EVENT button on the Receiver. We will demonstrate this when you come in for your screening session.
 - The marker maybe used to record significant 'events' you have identified i.e. ingestion of the Capsule, a meal, a bowel movement.
 - Pressing the EVENT button on the Receiver inserts a marker in the test data record but it does not identify the type of 'event'. Therefore, it is essential that you manually write down all 'events' in the Diary that is given to you. Use the time displayed on the Receiver to record 'events'.