The Heidelberg™

Informed Consent Form

Please answer the following questions on your past or present medical history with (Y)ES or (N)O, **If you are not sure, answer (Y)ES**

Could you be pregnant, or are you attempting to become pregnant? _____

Have you ever had or do you currently have any of the following?

_____ Chest Surgery or heart transplant surgery
_____ Heart Failure
_____ Heart Disease
_____ Vagotomy
_____ Tracheotomy or tracheostomy
_____ Oesophageal trauma
_____ Unsuccessful OGD (oesophageal gastro–duodenoscopy or gastroscopy)
_____ Roemheld's syndrome
_____ Symptoms of dysphagia
_____ Kilian's Dehiscence
_____ Pharyngeal pouch (Zencker's diverticulum)
_____ Hiatus Hernia
_____ Crohn's disease
_____ Any recent abdominal surgery
_____ A colostomy or ileostomy bag
_____ Haematemesis or Malaena
_____ Ulcerative Colitis

Are you presently taking any of the following prescription medications?

Antibiotics ☐ **(tick as applicable)**
Proton Pump Inhibitor ☐ **(tick as applicable)**
Antihistamines ☐ **(tick as applicable)**

I, _____ hereby consent and authorise the clinician at:
(Write name in bold capitals)

_____ to administer the tethered capsule as

part of the Heidelberg Test to:

Me ☐ **(tick as applicable)**
My child ☐ **(tick as applicable)**
My relative/associate ☐ **(tick as applicable)**
(for whom I have power of attorney over).

_____
(Name of patient in bold capitals)

In doing so, I hereby acknowledge the following (on behalf of the represented patient who will be expressed in the first person):

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- I understand that I may perceive an initial increase in nausea like symptoms during or immediately after the treatment due to stimulation of the gag reflex.
- I understand that I may perceive a soreness of the back of the throat due to the effects of the tether as it rubs against the inside of the back of the throat
- I have been given the opportunity to ask any questions I might have regarding the Heidelberg and the clinician has answered my questions.
- I have informed the clinician of my current health status and therapies and I agree that it is my responsibility to keep the clinician aware of changes in my condition, or therapies, for every session.
- I understand that the process of swallowing the capsule with a tether attached may feel unnatural and I will make every effort to remain calm and allow the clinician to guide me through the process by not making any sudden movements or panic during the procedure.
- I have been informed that I may refuse this diagnostic test at any time, or even terminate the test whilst undergoing it by asking the clinician to stop.
- If any unforeseen conditions arise during the course of this diagnostic test, I do hereby authorise/request the staff to perform such additional procedures and/or to render such procedures/treatments as may be deemed necessary at that time.
- In the event that the tethered capsule procedure fails, I do hereby authorise/request the staff to cut the tether, allowing the capsule to be consumed by myself in order to carry out the test, despite the risk of the capsule being dumped through the pyloric sphincter, which could render the test inadequate and resulting in my having to pass the capsule through natural means or having the capsule remain in the gut without being passed.
- I confirm that I have answered all the questions above truthfully and have read and understood all the instructions.

Authorised Signature:

_____

_____ _____

Date **Clinician Signature**