

Mock IRB Agenda 9/19/2014

HUM009876543: Safety and Initial Efficacy Study of the FIXIT Rx for Treatment of Benign Prostatic Hyperplasia

Primary Reviewer: Stephan Taylor

Submission Type: New Study

Current Benefit and Risk: Minor Increase over Minimal Risk with Potential Direct Benefit

Adult Consent Type: Comprehensive Written

Sponsor External, Industry

Internal Funding None

FDA Regulated: Yes

Device: Non-Significant Risk

Study Purpose: The purpose of this research study is to show whether an investigational device called the FIXIT RX is safe and works to relieve the narrowing of the urethra to improve urine flow in men with an enlarged prostate gland. It does this by using very intense, low duty-cycle ultrasound pulses (sound waves). These pulses generate extreme pressures within the prostate that leads to the formation of micro bubbles. The vibration caused by these micro bubbles reduces the prostate cells to loose slurry which is then eliminated from the body. The end result is a prostate which has much less bulk than prior to treatment. This is not a treatment for cancers. It is an experimental procedure and an experimental treatment. The device has not been approved by the U.S. Food and Drug Administration (FDA) for commercial use. Men volunteering in this study will be the first people ever treated with this device. All men in this study who meet all eligibility criteria will be treated with the device. The study will look at whether the investigational device is safe and works to treat the enlarged prostate gland as intended.