

**CONFIDENTIAL WHEN COMPLETE**



## **ROSSINI 2: Reduction Of Surgical Site Infection using several Novel Interventions**

*A phase III, multi-arm, multi-stage (MAMS), pragmatic, blinded (patient and outcome assessor), multicentre, randomised controlled trial (RCT) with an internal pilot, to evaluate the use of several in-theatre interventions, alone or in combination, to reduce SSI rates in patients undergoing abdominal surgery.*

### **INFORMED CONSENT FORM**

**Version 4.0, 24<sup>th</sup> February 2023**

**Site ID:**

**Patient ID:**

**Patient Initials:**

**Principal Investigator:**

***Please initial  
inside each box***

1. I confirm that I have read and understood the patient information sheet, dated \_\_ / \_\_ / \_\_ \_\_ version number \_\_\_\_\_ for the **ROSSINI 2** trial. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected. I understand that if I withdraw from the **ROSSINI 2** trial, data collected up to my time of withdrawal may still be used. ☐
3. I understand that relevant sections of my medical notes and data collected during the trial may be looked at by individuals from the **ROSSINI 2** research team, representatives of the sponsor, from regulatory authorities or from the NHS Trust, where this is relevant to my taking part in this research. I give permission for these individuals to have direct access to my records. ☐
4. I understand that information about me and my progress, including long term follow up data, will be supplied in confidence to the trial coordinators at the University of Birmingham Clinical Trials Unit (BCTU) by my own doctors for use in the **ROSSINI 2** Trial. ☐
5. I agree that my GP will be informed of my participation in this trial. ☐

**CONFIDENTIAL WHEN COMPLETE**

6. I agree that, if needed, I can be contacted via telephone, email or post, by staff at my hospital or by research staff at Birmingham Clinical Trials (BCTU) to aid in the completion of any questionnaires whilst I am participating in the **ROSSINI 2** Trial. ☐
7. Data collected that contains my address, telephone number and email *e.g. Contact Form* and data collected that identifies me by name, *e.g. Consent Forms*, will be transferred from where it is collected and will be stored at the **ROSSINI 2** Trials Office at the University of Birmingham, Birmingham Clinical Trials Unit (BCTU), if requested. I agree to the transfer and storage of this data. ☐
8. I agree to the information held and maintained by NHS England, together with current and future UK NHS bodies, being used in the future to help contact me or to provide information about my long-term health status and health care. For this purpose, I agree to the University of Birmingham BCTU holding my name, gender, date of birth and NHS number. ☐
9. I accept that, in the unlikely event of loss of my capacity, the research team will retain my personal data already collected and will continue to use this data for the sole purposes for which consent was sought. ☐
10. I have read and understood the information in the patient information sheet about what will happen with my personal data collected for this trial. I understand that the information collected about me may be used to support other related research in the future, and may be shared anonymously with other researchers. ☐
11. I agree to take part in the **ROSSINI 2** trial and understand that I may be randomised to receive any, all, or none of the interventions under investigation. ☐

\_\_\_\_\_  
*Name of Patient*

\_\_\_\_\_  
*Date*

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Name of Person taking Consent*

\_\_\_\_\_  
*Date*

\_\_\_\_\_  
*Signature*

**When completed please provide a copy to the participant, forward a copy to the **ROSSINI 2** Trials Office (if requested), retain a copy in the patient's medical notes and file the original in the **ROSSINI 2** Investigator Site File.**