Dear Dr <GP Name>

Your patient, named above, has given their consent and subsequently been enrolled in the **ROSSINI** trial whilst undergoing treatment at this surgical unit.

The **ROSSINI** trial (Reduction in Surgical Site Infection using a Novel Intervention) is a prospective, multicentre, observer-blinded trial which aims to establish if the use of a wound-edge protection device in adult patients undergoing midline laparotomy experience a lower rate of surgical site infection (SSI) than those cases not utilising the device. Secondary issues explored include establishing the efficacy of the device against various degrees of wound contamination and patient comorbidity, as well as assessing the cost-effectiveness of the device.

All adult patients undergoing laparotomy (both elective and emergency cases) under the care of a participating surgeon are being approached to enter the study. Patients who agree to take part (after full counselling and provision of a patient information leaflet) are then randomised immediately prior to their operation with a 1:1 ratio of intervention (device used) to control (no device) arm allocation. Follow-up is according to a predetermined schedule, using specific proformas to collect the blinded wound review data. Your patient will be asked to attend the hospital at around 30-33 days post-operation for a final clinical wound assessment. This visit may be combined with their routine follow-up appointment or may require a separate attendance. They will also be asked to complete a questionnaire discussing any wound problems they
experienced in the interim, including whether they needed to see any doctors in the community regarding their wound or its healing.

Due to the blinded nature of the study we are unable to inform you which arm your patient was randomised to (and thus whether a device was used during their operation). This information will be made available, if desired, once your patient’s involvement is complete (at around 60 days post-operation).

We request that in order to achieve as accurate a representation of true SSI rates as possible, please consider the following:

- Please continue to prescribe antibiotics for obvious wound infections as you would normally, but do take a pus swab from the wound prior to commencing treatment. We will be able to follow-up these microbiology results to identify pathogens later on.
- We are providing extra clinics / accessibility to local investigators for patients participating in the trial. Any equivocal wounds or other wound-related issues can be seen at short notice – please contact us as below.

If you require any further information about the ROSSINI trial, please either contact me or the ROSSINI study office at the University of Birmingham Clinical Trials Unit.

Many thanks,

Name………………………………………………………………………………………………………………………………………………………………………………
Position……………………………………………………………………………………………………………………………………………………………………………………
Contact Details…………………………………………………………………………………………………………………………………………………………………………

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