



CASE REPORT FORMS

Identifying Details

Site ID:	
Date of Birth: <i>e.g. 31-JAN-2017</i> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Patient's Initials: <i>First, Middle, Last</i> <input type="text"/> <input type="text"/> <input type="text"/>
Sex: <i>(Please tick one)</i> <input type="radio"/> Male <input type="radio"/> Female	
NHS Number: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
ROSSINI 2 Trial ID: <i>(Provided once randomised)</i> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	



Initials: Site ID:

UNIVERSITY OF
BIRMINGHAM



BASELINE

PART A - Consent

Has the patient given valid informed consent? ☐ No ☐ Yes

If Yes, please provide date of consent: Version number of Consent Form used:

How was consent obtained: *(Please tick one)*

☐ In Person (Face to Face) ☐ Remote (Postal/ Telephone/ Email)

PART B - Quality of Life Questionnaire

Please ensure a Quality of Life (QoL) questionnaire (EQ-5D-5L) has been completed after consent but prior to Surgery.

Has the patient completed an EQ-5D-5L questionnaire? ☐ No ☐ Yes

If No, please specify why not:

PART C - Baseline Data

Demographic data and pre-operative assessment.

Date of Baseline Assessment: *(Should be collected prior to Randomisation and Surgery)*

BMI: *(If BMI is not available, please provide Height and Weight)* kg/m²

Height: cm Weight: kg

American Society of Anesthesiologists grade: *(Definitions provided on next page)* *(Please tick one)*

☐ Grade I ☐ Grade II ☐ Grade III ☐ Grade IV ☐ Grade V

Is the patient known to have diabetes? ☐ No ☐ Yes If Yes, how is it managed? *(Tick all that apply)*

☐ Diet Controlled ☐ Tablet Controlled ☐ Insulin Controlled

What is the patient's smoking or vaping (e-cigarette) status? *(Tick all that apply)*

☐ Current smoker (or stopped smoking less than 6 weeks ago)

☐ Current vaper (or stopped vaping less than 6 weeks ago)

☐ Ex-smoker (stopped smoking more than 6 weeks ago)

☐ Ex-vaper (stopped vaping more than 6 weeks ago)

☐ Never smoked or vaped

Is the patient on any immunosuppressive therapy? *(oral or inhaled immunosuppressive medication including steroids, or immunosuppression due to pre-existing medical condition)*

☐ No ☐ Yes

Is the patient clinically jaundiced? *(serum bilirubin >50 µmol/L)* ☐ No ☐ Yes

Has a serum albumin level been measured in the past 6 months? ☐ No ☐ Yes

If Yes, please provide the most recent serum albumin level: *(5-80 g/L)* g/L

Does the patient have an active malignancy? *(this does not have to be the condition being operated on)* ☐ No ☐ Yes

Does the patient have any previous documented MRSA colonisation *(at any site)*? ☐ No ☐ Yes

If Yes, please provide date of diagnosis: *e.g. 31-JAN-2017* And site of MRSA colonisation:

Initials: Site ID:

American Society of Anesthesiologists physical status classification system (modified for ROSSINI 2)

GRADE I - A normal healthy patient

GRADE II - A patient with mild systemic disease

GRADE III - A patient with severe systemic disease

GRADE IV - A patient with severe systemic disease that is a constant threat to life

GRADE V - A moribund patient who is not expected to survive without the operation

Completed By

Full Name: (PRINT NAME)

Signature:

Position:

Date: e.g. 31-JAN-2017 - -

Thank you for completing this CRF. You are now required to transcribe this information onto REDCap (<https://bctu-redcap.bham.ac.uk/>). This CRF can be used as source documentation and filed in the patient's records.