RACER

Robotic Arthroplasty:
A Clinical and cost Effectiveness
Randomised controlled trial

Randomisation & Day of Surgery Instruction Booklet

This booklet contains the instructions, randomisation contact information and study procedures for the Day of surgery. If you have any queries please contact the central study team at:

Racer@warwick.ac.uk

If Randomisation is being performed by the treating surgeon please remember that *no documents* should be shared with anyone outside of theatre and the allocation must not be discussed with the participant or Research Nurse.

If Randomisation is being performed by an Un-Blinded Research Nurse the randomisation form can be placed in this pack and handed to the treating surgeon, ensuring blinding is maintained. Again, the allocation *must not* be discussed with the participant or anyone outside of Theatre.

Please remind recovery and ward staff this is a blinded trial and to not disclose treatment allocation to the patient or unauthorised persons.

For a printable version of this pack go to:
https://warwick.ac.uk/fac/sci/med/research/ctu/trials/current/racer/

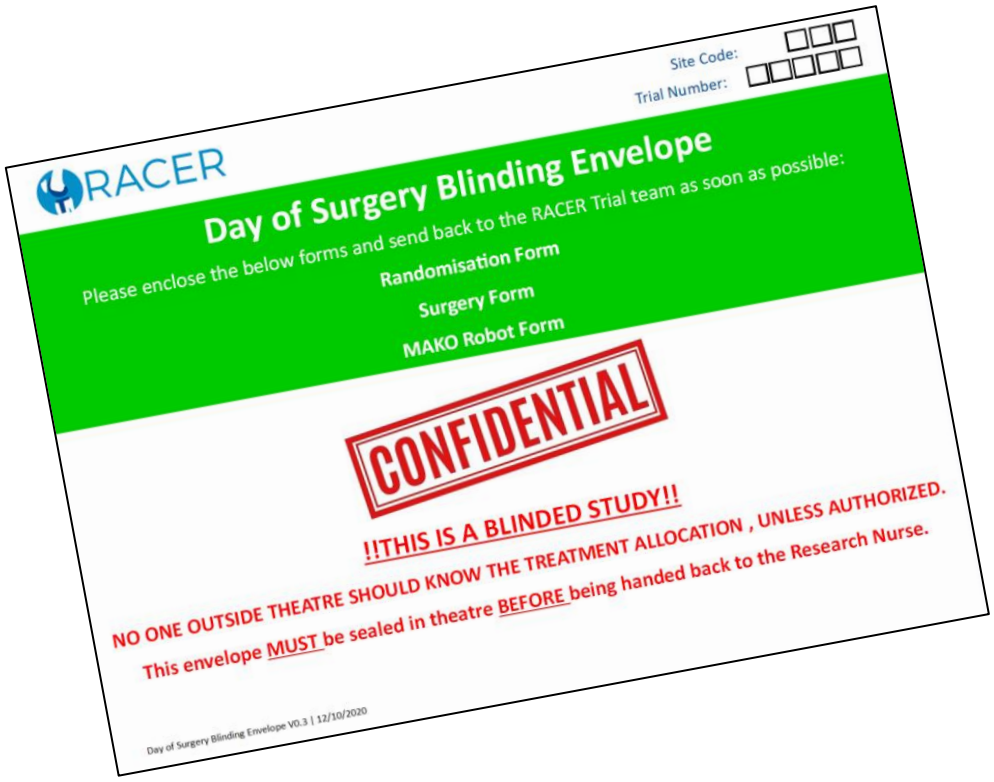
Contents

Forms expected to be used on the day of surgery:

- ☐ **Randomisation Form**
- ☐ **Surgery Form**
- ☐ **MAKO Robot Form**

Please enclose these forms in the Day of Surgery Blinded Envelope provided even if they have not been completed.

THIS MUST BE SEALED IN THEATRE TO ENSURE BLINDING REMAINS INTACT.



Note: the sealed Day of Surgery Blinded Envelope should be sent back to the RACER Trial team using the pre-paid envelopes supplied.

Printable versions of these forms can be found at: https://warwick.ac.uk/fac/sci/med/research/ctu/trials/current/racer/

GCP Awareness

All Staff with access to Trial paperwork and the Trial Database must be aware of the below GCP principles:

Good Clinical Practice (GCP) - 13 Principles

GCP is an internationally agreed **ethical and scientific quality standard** for designing, conducting, recording and reporting trials that involve the participation of **human subjects**.

Working to GCP principles provides assurance that the **rights, safety and well-being** of trial subjects are protected, we are working ethically and in accordance with the principles that have their origin in the **Declaration of Helsinki**, and that the clinical trial **data is credible.**

1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).
2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
3. The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.
4. The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.
7. The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
9. Freely given informed consent should be obtained from every subject prior to clinical trial participation.
10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
12. Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.
13. Systems with procedures that assure the quality of every aspect of the trial should be implemented.

Online Randomisation

- To begin the online randomisation you will need to confirm the patient's details. You will need access to initials, DOB, BMI, hospital number and gender.
- To randomise a RACER participant open the database via

https://ctu.warwick.ac.uk/racer

Your log in details are:

Username: **Password:**

- Please select the participant who is due to be randomised. You can filter by TNO, date of surgery or DOB etc. if required.
- You can now begin to randomise the patient. You will need to state the knee being randomised.

24/7 Telephone Line

- Before you call to randomise the patient please ensure that you know the participant's Trial Number and knee to be randomised.
  (Having a completed randomisation form will ensure you have the required information to hand)
- Please call **+44 (0) 24 7526 2666** to randomise the patient.
- **Your site PIN number:**
- You only need to follow the instructions given as you will be guided through the randomisation process on this call.

Emergency Manned telephone system

Only to be used if the 24/7 telephone system fails

Please contact the Randomisation officer via **02476 150 402**

You will need:

- Patient initials
- Hospital number
- Date of birth
- BMI
- Name of operating surgeon

Online Operation Note

- After surgery we advise you to use the blinded operation note template provided by the RACER Trial office for the participant's medical notes regardless of the intervention allocated.

- To complete the online operation note, please follow the link on the template operation note and enter the individual log in details provided to you by the RACER Trial office. If you do not know your log in please contact:

RACER@warwick.ac.uk

- The Online operation note should be completed *as soon as possible* as this information could be required for safety purposes.

Blinding Note

- Please **do not** discuss the allocation the participant has received and avoid writing it on theatre lists.
- For patients that are awake during the operation the use of headphones and draping to conceal the type of surgery (conventional/robot assisted) should be considered regardless of allocation within the trial to maintain blinding.
- Randomisation may be carried out by any member of the theatre staff or an un-blinded research nurse.
- As the Randomisation CRF will include the participants allocation this must be stored in the blinding envelope and returned to the RACER Trial Team.
- The MAKO Robot form must be completed during/after surgery and also placed in the blinding envelope to be returned to the trial team.
- The Surgery Form does not contain blinded information, but does need to be returned to RACER Trial Team, this can also be placed in the confidential envelope for ease.
- Once the completed forms have been placed into the blinding envelope this can then be sealed and handed to the Research Nurse to be returned to the RACER Trial Team as soon as possible.

Important!

- Ensure an electronic copy of the Blinded Operation note template is emailed to the theatre computer/surgeon for the Surgeon to use.
- Ensure that the confidential envelope is sealed in theatre and returned to the RACER central office promptly.
- Ensure the MPS rep downloads the images from the MAKO onto the hard drive provided by the trial team—this hard drive is to be present in every RACER surgery to protect blinding.

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Affix Trust Logo/Office details sticker here

RACER Trial Team

Tele: XXX XXXX XXXX

Racer@warwick.ac.uk