

RACER Documents Version Control Log

Document Name	Document Version	Document date	Date Approved by REC	Amendment No.	Reason for change to document
RACER Protocol	3	26-Nov-21	25-Jan-22	SA2	
Patient Information Sheet (Main)	4	26-Nov-21	25-Jan-22	SA1	
Patient Information Sheet Learning Effect Sub-Study	4	26-Nov-21	25-Jan-22	SA2	
Study Summary Sheet	2	03-Sep-21		-	
Patient Consent Form (Main)	3	26-Nov-21	25-Jan-22	SA2	
Patient Consent Form – Learning Effects Study	3	26-Nov-21	25-Jan-22	SA2	
GP Letter (Main)	1	04-Mar-20	29-Jul-20	-	
GP Letter Learning Effects Study	1	27-May-20	29-Jul-20	-	
Patient ID Card	1.3	13-Oct-20	09-Nov-20	SA1	
Rehabilitation Booklet	1.3	06-Oct-20	09-Nov-20	SA1	
Registration Form (x3 parts – Eligibility Confirmation/ Informed Consent Confirmation/ Registration)	2	01-Nov-21		-	
Patient Contact Details	2	24-Jan-22		-	Removed NOK address
Baseline CRF	3	24-Feb-21		-	
Randomisation CRF	1.1	09-Nov-20		-	
Surgery Form	3	10-Nov-21		-	Updated according to study requirements
Learning Effect Study Surgery Form	3	10-Nov-21		-	Updated according to study requirements
Imaging Form	2	10-Feb-21		-	
In-patient Blood Loss and Opioid CRF	1.1	15-Sep-20		-	
MAKO Robot Form	3	14-Jul-21	-	-	Updated according to study requirements
Questionnaire Cover Letter	2	20-Sep-21	25-Jan-22	SA2	
Medical Notes Statement	2	24-Feb-21		-	
Medical Notes Sticker	2	24-Feb-21		-	

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Baseline Questionnaire	3	15-Sep-21	25-Jan-22	SA2	
Post-operative Pain Questionnaire	2	14-Sep-20	09-Nov-20	SA1	
Six Week EQ5D-5L Questionnaire	3	15-Sep-21	25-Jan-22	SA2	
RACER 3 Month Follow up Questionnaire	3	15-Sep-21	25-Jan-22	SA2	
RACER 6 Month Follow up Questionnaire	3	15-Sep-21	25-Jan-22	SA2	
RACER 12 Month Follow up Questionnaire	3	15-Sep-21	25-Jan-22	SA2	
RACER 24 Month Follow up Questionnaire	3	15-Sep-21	25-Jan-22	SA2	
RACER 5 Year Follow up Questionnaire	3	15-Sep-21	25-Jan-22	SA2	
RACER 10 Year Follow up Questionnaire	3	15-Sep-21	25-Jan-22	SA2	
SAE Initial Form	1	23-Jul-20	-		
SAE Continuation Form	1	29-Jul-20	-		
SAE Follow up Form	1	23-Jul-20	-		
SAE Evaluation Form	1	01-Jul-20	-		
Adverse Event Form	2	01-Oct-21	-		
Site Safety Reporting Procedure	1	02-Feb-21	-		
Screening Log	2.1	29-Mar-21	-		
Delegation Log	3	13-Aug-21	-		Added code Q for Associate PI
Delegation of Responsibilities Codes	3	13-Aug-21	-		
Participant Withdrawal (Main)	1	23-Jul-20	-		
Learning Effect Study Participant Withdrawal	1	23-Jul-20	-		
Protocol Deviation	1	01-Jul-20	-		
Note to File	1	28-Apr-20	-		
Notification of Death	1	28-Apr-20	-		
Surgical Manual	4	03-Oct-20	-		
Physiotherapy Manual	1.1	25-Sep-20			
Imaging Manual	2	08-Mar-21	-		-

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Operation Note (Online CRF)	1	02-Oct-20	-	
Protocol Summary Flow Chart	1	30-Jul-20	-	
Study Contacts Sheet	4		-	Change of staff
Evidence of Surgeon Qualifications Log	1	05-Jan-21	-	
Evidence of Surgeon Qualifications Process	1	22-Dec-21	-	
RACER-K_Template Blinded Operation Note	1	01-Oct-20	-	-