

**Queen Mary Ethics of Research Committee**

Joint Research Management Office (JRM0)

Research Ethics Facilitators

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**APPLICATION FORM FOR INDIVIDUAL RESEARCH PROJECT APPLYING FOR DEVOLVED SCHOOL RESEARCH ETHICS COMMITTEE (DSREC) APPROVAL**

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| Please complete this form if you plan to undertake a research project involving human participants which is classified low-risk (see [guidance list for studies NOT categorised as low-risk](https://www.ukri.org/councils/esrc/guidance-for-applicants/research-ethics-guidance/ethics-reviews/research-that-may-require-full-ethics-review/)). The completed form should be submitted to the IHSE Peer Review and Devolved Ethics Committee. Attach a copy of the Participant Information Sheet and the Consent Form or other material that will be used in the consent process. The [University’s Participant Information Sheet and Consent Form templates](http://www.jrmo.org.uk/performing-research/conducting-research-with-human-participants-outside-the-nhs/#applications) must be followed. Any relevant documents, such as study protocol, interview guide or survey questions, should be attached to the form. Before submitting, you should ensure that you have read and understood the [JRMO’s research ethics web page.](http://www.jrmo.org.uk/performing-research/conducting-research-with-human-participants-outside-the-nhs/) For additional support please contact ihse-research@qmul.ac.uk. |

**Section 1 – Basic study details**

**1a. Full study title**

Evaluation of a structured training programme in robotic-assisted orthopaedic surgery for theatre (scrub) nurses

**1b. Study type**

This is a:

QM Staff study

QM Postgraduate Research study

QM Taught Postgraduate student study (e.g. MA, MRes, MSc, LLM)

QM Undergraduate student study

**1c. Details of the existing generic teaching module ethical approval (to be completed by DSREC Administrator)**

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| Project title of the approved generic research ethics application:  Reference number of the approved generic application: |

**1d. Details of the lead Investigator**

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| Title and full name: Mr Thomas David Stringfellow MRCS BMBS BMedSci(hons) (TDS)  School or Institute: Institute of Health Sciences Education  Email: **ha231360@qmul.ac.uk**  Programme of study: MA Medical Education  Module code: IHS7015 Dissertation |

**Qu 1e-1g Student Studies only:**

**1e. Details of the Course Leader**

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| Title and full name: Dr Michael Page  School or Institute: Institute for Health Sciences Education  Email: m.page@qmul.ac.uk  Telephone: 07793143173 |

**1f. Details of the Supervisor**

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| Title and full name: Dr Michael Page (MP)  School or Institute: Institute for Health Sciences Education  Email: m.page@qmul.ac.uk  Telephone: 07793143173 |

**1g. Details of the Queen Mary Student Investigator(s)**

|  |
| --- |
| Title and full name: Mr Thomas David Stringfellow MRCS BMBS BMedSci(hons) (TDS)  School or Institute: Institute of Health Sciences Education  Email: **ha231360@qmul.ac.uk**  Programme of study: MA Medical Education  Module code: IHS7015 Dissertation |

**1h. Details of other external collaborator(s) who will be contributing to the study *(if applicable)***

***Note to applicant:*** *Duplicate box for multiple collaborators*

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| Title and full name: Mr Robert McCulloch FRCS, (RM)  Position held: Consultant Orthopaedic Surgeon  Organisation, postal address and website if available:  <https://www.rnoh.nhs.uk/health-professionals/consultants/mr-rob-mcculloch>  Joint Reconstruction Unit, Royal National Orthopaedic Hospital, Brockley Hill, Stanmore, HA7 4LP  Email: Robert.mcculloch@nhs.net  Telephone:07828994208  Role in study: Clinical Supervisor, NHS Research Supervisor |

**1i. Estimated study start date**

15/01/2024

**Estimated study end date**

01/07/2024

**Section 2 – Risk filter**

**2. For your study to be eligible for DSREC approval, you must confirm the following by ticking the boxes:**

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| **My study does not examine a topic that may be considered sensitive** **such as:**   * sexual behaviour * illegal or political behaviour * experience of violence, abuse or exploitation * mental health * gender, ethnicity or immigration status.   ***Note to applicant:*** *Gender and ethnicity questions can still be part of the demographic questions asked.*  **My study does not involve any of the following participant groups:**   * children and young people under 18 * potentially vulnerable people or groups (i.e. people with a learning disability or cognitive impairment, older adults or individuals in a dependent or unequal relationship). * participants who may be identifiable in the material used or generated (i.e. visual or vocal methods producing images or sound recordings) * interviews with people holding high office (elite interviews). * participants recruited or identified through the internet or social media where the understanding of privacy in these settings is ambiguous (i.e. in ‘closed’ discussion groups where there is potential for quotes and visual images to be identifiable). * participants who may be classified as vulnerable for any other reason other than those given above.   **My study does not involve any of the following interventions:**   * administration of licensed medicinal products * use of medical devices (i.e. Magnetic Resonance Imaging) * ingestion of any substance by participants (i.e. food substances, supplements or vitamins) * physical interventions (i.e. exercise or hypnotherapy) * collection of human tissue samples   **My study design does not involve deliberately deceiving participants**  ***Note to applicant:*** *Deception occurs when a researcher offers false information to participants or intentionally misleads them about key aspects of the research.*  **My study does not involve access to records of personal or sensitive confidential information, including biometric and health data, concerning identifiable individuals**  **My study does not offer disproportionate financial inducements (beyond travel reimbursements and expenses) to participants?**  ***Note to applicant:*** *Undue inducements are excessively attractive offers or disproportionate large payments that persuade participants to take undue risks or volunteer against their better judgement.*  **There is no risk that my research may result in participants becoming distressed**  **My study does not involve issues that may be classified as security sensitive**  ***Note to applicant:****Research commissioned by the military; or commissioned under an EU security call; or research concerning terrorist or extremist group can be classified as security sensitive.*  **My study does not involve visits to websites, storage or transmission of documents that might be associated with extremist, or terrorist, organisations** |

If you HAVE SELECTED ALL of the above, complete this application form and submit your application to the DSREC or designated School Ethics Lead of the School your Supervisor belongs to, who will consider this application form and any participant documentation ([written using QMERC templates](http://www.jrmo.org.uk/performing-research/conducting-research-with-human-participants-outside-the-nhs/documents-guidance-and-resources/)), address any concerns, and determine whether your individual application adheres to the specifics of the existing generic teaching module ethics approval.

If you have NOT SELECTED ANY OF THE ABOVE, you should stop completing this form as it is not eligible to go through the low-risk approval route. Please complete a [QMERC research ethics application form](http://www.jrmo.org.uk/performing-research/conducting-research-with-human-participants-outside-the-nhs/documents-guidance-and-resources/) and submit the form and any participant documentation (written using QMERC templates), to the Research Ethics Facilitators ([research-ethics@qmul.ac.uk](mailto:research-ethics@qmul.ac.uk)).

**Section 3 – Research design**

**3a. Describe the research aim(s) and research design of your study.**

**Background**

Robotic-assisted joint replacement surgery is an example of a technological innovation that has been shown to improve the patient outcomes of complex hip and knee replacement surgery1,2, its’ use is therefore becoming more widespread in UK NHS hospitals. Robotic surgical systems require surgeon and scrub nurse training as the workflow and setup is different to that of conventional techniques. These skills are often especially unfamiliar to scrub nurse colleagues3. When robotics are first introduced, this can initially reduce the theatre list efficiency, and potentially result in fewer cases performed in an operating session. It is therefore advantageous to examine ways to best train our scrub nurses in these new techniques as we continue to tackle the huge elective care backlog and strive for better efficiency.

Surgeons typically have access to industry-delivered training, cadaveric workshops, and the opportunity to visit experienced surgeons nationally and internationally to learn these techniques. These learning opportunities are not currently offered to scrub nurse colleagues. Training in new equipment, instrumentation and implants for scrub nurses is often unstructured, ad-hoc and, in the UK, is largely apprenticeship-driven4,5. Often there are industry-sponsored sessions but no structured programme delivered by the institution itself.

Technology-enhanced learning has been recognised by NHS England as a priority in designing and delivering healthcare professional teaching as a way to maximise benefit to learners and the health service6. This project will combine traditional ‘hands on’ teaching with equipment and instrumentation and digital content for setup and instrument familiarisation and steps of robotic joint replacement procedure that can be accessed asynchronously and as part of a structured training programme.

**Research Question**

How effective is a structured training programme in development of technical and non-technical skills in robotic-assisted joint replacement surgery for scrub nurses?

**Objectives**

1. Assess scrub nurses’ knowledge of principles, instrument function, and sequence of steps in robotic joint replacement before and after a structured training programme.
2. Assess practical skills by measuring time taken to setup for robotic joint replacement cases in a simulated environment before and after a structured training programme.
3. Evaluate usage, value and role of asynchronous video, written and image content to support the above objectives.
4. Gather feedback on the value of structured training in this clinical setting and nurses’ preferred methods to learn new technical skills.
5. Investigate nurses’ opinions about introduction of a surgical robotics programme via an actor network theory lens.7

**Methods**

An interrupted time series study design8 will be used to monitor the performance of a novice group of scrub nurses before and after a structured training programme. An interrupted time series design is a strong quasi-experimental design often used to evaluate new programmes or technologies where a randomised controlled trial is not feasible9,10. In this case, with a novice population of scrub nurses it was decided denying access to training to half to cohort was not equitable and likely relatively low numbers would not be powered to detect a significant difference. Within our institution we have had a recent expansion in scrub nurses to coincide with operating theatre expansion. Mixed methods will be used to allow triangulation of observations in quantitative data to be compared with and explained with the aid of more interpretivist methodologies11.

The following data collection tools will be used:

* **Baseline demographic data collection** and prior experience of all participants via online form (Microsoft Forms). Fields: nursing degree / qualification, experience in robotic cases and time in practice. In order to screen for inclusion criteria (experience of fewer than 5 robotic cases) and describe the sample.
* **Pre and post training programme knowledge test** of questions written by surgeons, experiences scrub nurses and industry representatives.
* **Simulation exercise** to setup for a robotic joint replacement case measuring time to complete each step – completed before and after the training programme and number of prompts needed. Patients not involved, this will assess setup of the robot system and total hip and knee replacement instruments in a simulated theatre environment.
* **Monitoring Confounders** - over the 6-week programme, each nurse’s case exposure will be self-reported with an anonymised logbook of cases they have scrubbed for. Access to asynchronous content will be monitored with individualised web links to monitor who views the content and when. These data are important to collect to account for variable exposure in an open system workplace experiment12.
* **Qualitative focus group interviews** to explore opinions about robotics, how scrub nurses prefer to learn practical skills and to evaluate the training programme. One in the first and one in the last week of the programme, each one hour with 5-10 scrub nurse participants (self-selected from the study cohort). The objects of discussion will be the online content videos on setting up the robotic arm and the robotics system itself. MS teams focus groups with audio recording and transcription (analysis as below). Questions to include: *How do you feel about using robotics in theatre?* *If you were learning a new skill to use in your practice, how would you learn this?* *How would you prepare for a case with new instruments or equipment? How do you use online resources to help prepare for a case? How would you change the resources you had access to as part of this study and is there anything else that would have been useful?*

**Data analysis**

Quantitative data for each participant will be collated in Excel (Microsoft) and then assessed for normality and basic descriptive statistical tests performed in SPSS (IBM), statistical significance testing and regression modelling will be completed in SPSS (IBM). For normally distributed data, paired T-tests, and for non-normally distributed data Wilcoxon rank tests will be used. Qualitative transcript data will be analysed using Braun and Clarke’s reflexive thematic analysis13 with nVivo software following audio recording transcription. The thematic analysis of opinions about robotics will be viewed through an actor network theory lens, this theory described by Latour can be interpreted to view novel technologies as actors in a workplace or learning ecosystem and examines interplay between them and users7.

**References**

1. Ng N, Gaston P, Simpson PM, Macpherson GJ, Patton JT, Clement ND. Robotic arm-assisted versus manual total hip arthroplasty. Bone Joint J [Internet]. 2021 Jun 1;103-B(6):1009–20. Available from: https://online.boneandjoint.org.uk/doi/10.1302/0301-620X.103B6.BJJ-2020-1856.R1

2. Zhang J, Ndou WS, Ng N, Gaston P, Simpson PM, Macpherson GJ, et al. Robotic-arm assisted total knee arthroplasty is associated with improved accuracy and patient reported outcomes: a systematic review and meta-analysis. Knee Surgery, Sport Traumatol Arthrosc [Internet]. 2022 Aug 6;30(8):2677–95. Available from: https://link.springer.com/10.1007/s00167-021-06464-4

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4. Radford EJ, Fotis T. The lived experiences of operating theatre scrub nurses learning technical scrub skills ‘I’m doing this right, aren’t I? Am I doing this right?’ J Perioper Pract [Internet]. 2018 Dec 14;28(12):355–61. Available from: http://journals.sagepub.com/doi/10.1177/1750458918780159

5. Gillespie BM, Chaboyer W, Wallis M, Chang HYA, Werder H. Operating theatre nurses’ perceptions of competence: A focus group study. J Adv Nurs. 2009;65(5):1019–28.

6. NHS England. Technology Enhanced Learning (TEL) [Internet]. 2022 [cited 2023 Nov 2]. Available from: https://www.hee.nhs.uk/our-work/technology-enhanced-learning/digital-education

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10. Ramsay CR, Matowe L, Grilli R, Grimshaw JM, Thomas RE, Hudson J, et al. Comparison of six statistical methods for interrupted time series studies: empirical evaluation of 190 published series. BMC Med Res Methodol [Internet]. 2021;19(1):1–7. Available from: https://doi.org/10.1186/s12874-021-01306-w

11. Biesta GJJ. 19) Mixing Methods in Educational Research. In: Coe R, Waring M, Hedges L, Arthur J, editors. Research Methods & Methodologies in Education. 2nd ed. London, UK: SAGE; 2017. p. 159–65.

12. Biesta GJJ, van Braak M. Beyond the Medical Model: Thinking Differently about Medical Education and Medical Education Research. Teach Learn Med [Internet]. 2020;32(4):449–56. Available from: https://doi.org/10.1080/10401334.2020.1798240

13. Braun V, Clarke V. Section 3: successfully analysing qualitative data. In: Carmichael M, editor. Successful Qualitative Research: a practical guide for beginners. 1st ed. London: SAGE; 2013. p. 159–248.

14. Edwards TC, Patel A, Szyszka B, Coombs AW, Liddle AD, Kucheria R, et al. Immersive virtual reality enables technical skill acquisition for scrub nurses in complex revision total knee arthroplasty. Arch Orthop Trauma Surg [Internet]. 2021 Dec 28;141(12):2313–21. Available from: https://link.springer.com/10.1007/s00402-021-04050-4

**3b. Describe the key characteristics of your participants (for example, age, gender, course (MBBS, PA etc) and year of study). State and briefly justify the inclusion and exclusion criteria that will be used for both identification and recruitment of participants.**

**Participants**

Inclusion criteria: novice scrub nurses working within trauma and orthopaedic theatres, all post-primary nursing qualification, who do not have experience in robotic assisted orthopaedic surgery.

Exclusion criteria: scrub nurses experienced in robotic joint replacement surgery.

**3c. State the number of participants to be recruited and explain how the sample size was decided.**

Aiming for 15-20 participants. Another study examining to effectiveness of virtual reality (VR) training for scrub nurses in complex orthopaedic surgery recruited 15 participants and was powered to detect a 47% reduction in time taken to complete a VR procedure14. Within my institutional setting, we have a cohort of around 20 novice scrub nurses who would be eligible to participate following recent expansion of operating capacity.

**3d. Site(s) of the research study.**

**Royal National Orthopaedic Hospital NHS Trust (RNOH)**

Brockley Hill, Stanmore, Middlesex, HA7 4LP

Project approved by local quality improvement committee – no direct patient contact, exempt from NHS ethics REC approval using HRA decision tool (<https://www.hra-decisiontools.org.uk/research/result7.html>). Project discussed at RNOH research project evaluation panel 02/11/2023, **outcome: proceed as quality improvement project**.

**3e. How will potential participants be identified, approached and recruited?**

Presentation of project at nursing development study morning followed by ii) Display of break room QR code posters with expression of interest sign up link.

**3f. Please explain how you will obtain consent; who will seek it; what information is to be provided to potential participants about the study and how you will document consent.**

Following presentation of the project, potential participants have time to consider their taking part in the study, if they decide to go ahead they can express interest via an online web form. The demographic and experience data of each potential participant will then be reviewed, those who meet the inclusion criteria will be invited to take part in the structured teaching programme. In the first session, run by the principle investigator (TDS), there will be a further opportunity to ask questions prior to signing of QMUL consent forms and commencement of the study. University rooms will be used to deliver the programme, not the workplace premises.

**3g Describe how you will ensure anonymity and protect confidentiality of data.**

Each potential participant who returns an expression of interest form will be given an anonymised study ID which will be used for the remainder of the project. All data will be held on a password protected spreadsheet within the secure PI’s laptop (for a maximum of 2 years). It is necessary to keep a ‘key’ spreadsheet to allow participants to be identified by name to manage requests to withdraw and remove their data prior to final analysis. Password protected excel sheets will always be used. Audio files will be deleted 3 months after transcription of focus groups, survey, quiz and practical performance data will be deleted 2 years after project completion and dissertation submission. It is anticipated that the project will be written up for publication in an orthopaedic or nursing education journal to allow findings dissemination.

**3h. By checking the following boxes, I confirm that:**

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| Collection, secure storage and disposal of data will be undertaken in accordance with the specific generic approval and [University guidance and policies.](http://www.arcs.qmul.ac.uk/governance/information-governance/records-management/)  All personal data will be stored and processed in compliance with [data protection legislation](http://www.arcs.qmul.ac.uk/governance/information-governance/data-protection/gdpr/). |

**Section 4 – Ethical considerations**

**4a. Describe any ethical issues that might be raised by your study and how you will address these (i.e. explain the potential benefits and risks, if any, to the participants).**

There are potential benefits to scrub nurses who choose to take part, they will receive small group teaching in robotic joint replacement techniques to allow them to develop their skills under supervision in a simulated setting with access to asynchronous learning resources including video content, written materials and instrumentation crib sheets. In careful design of this project and its’ methodology, it was thought that a randomised design would not be equitable in this population where structured teaching is not routinely widespread. If any upsetting themes or issues arise in focus group interviews, participants will be directed RNOH’s staff support team for further assistance. However, this is very unlikely given the focus of these groups is to evaluate the teaching programme rather than discuss wider workplace issues.

As above, the NHS HRA decision support tool was used to confirm this project does not require formal NHS REC approval via the IRAS system.

This research is not intended to comprise an assessment of the job-related competence of the participants. The aim, as stated previously, is to evaluate a teaching programme for an orthopaedic robotics programme. In the unlikely event that unsafe or unprofessional practice is observed, I would be obliged to pass on such concerns to the nurse line manager within the operating theatre department. In summary, the project is assessing the programme of learning, not the individual performance of the scrub nurses.

**4b. By checking the following boxes, I confirm that:**

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| Participation is entirely voluntary. Refusal to participate requires no reason and will not affect the individual or their rights.  Presentation on aims and methods of study at nursing development day, followed by time for participants to consider taking part prior to consent. Entirely voluntary consent to take part.  Appropriate informed consent will be obtained from participants using the [University’s guidance, Participant Information Sheet and Consent Form templates.](http://www.jrmo.org.uk/performing-research/conducting-research-with-human-participants-outside-the-nhs/documents-guidance-and-resources/)  Please see participant information sheet and consent form attached to this application.  Participants will be provided in advance with a brief but complete description of the purpose of the study and what they should expect to happen if they decide to participate in the study.  As above, presented in nursing development day at RNOH.  Participants may withdraw from the study at any time. Requests for withdrawal of data will be facilitated as specified in the Participant Information Sheet.  Please see attached.  Participants will be asked for their consent to be photographed, videoed, audio-recorded, or observed.  Included in consent form.  Participants will not be identifiable in published or shared reports.  As per above and consent form. |

**Section 5: Declarations**

**5a. By checking the following boxes, I confirm that:**

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| The information in this form, including any supporting documentation is, to the best of my knowledge, complete and correct. I have attempted to identify and mitigate all risks that may arise in conducting this research and acknowledge my obligations as investigator and the rights of the participants.  I am responsible for notifying the School Research Ethics Committee of any amendments, minor or major, to the study.  I have read and understood the [Queen Mary Policy on Research with Human Participants](http://www.arcs.qmul.ac.uk/media/arcs/policyzone/QMUL-Research-with-Human-Participants-Dec-14-final.pdf) and the [Concordat to Support Research Integrity](https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2019/the-concordat-to-support-research-integrity.pdf).  The primary purpose of the study is submitting a report/dissertation for internal assessment. In the event of possible external publication, this will be made explicitly clear in the QMREC participant information sheet and consent form and the Supervisor who is acting as the Principal Investigator for the study will be informed.  I am responsible for reporting any unexpected deviations to study protocol or unexpected events which occur, to the School Research Ethics Committee. |

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Description automatically generated**Signature of Lead Investigator: ……………………………………………….………….........................................................

Print name: ………Mr Thomas Stringfellow…………………………………………………………………………………..

Date: ……19/12/2023…………………………………………………….......................................................



Signature of Supervisor (if a student study): ..……………………………………………………………………………...........

Print name: …M T J Page…………………………………………………………..……………………………………………

Date: …19/12/23…………………………………………………….............................................................................