FULL/LONG TITLE OF THE STUDY	Quantitative assessment of image quality in rectal cancer MR images when using artificial intelligence reconstruction techniques
SHORT STUDY TITLE / ACRONYM	Assessing the use of artificial intelligence in rectal magnetic resonance imaging.
PROTOCOL VERSION NUMBER AND DATE	**Version 0.3**
IRAS Number:	345225
JRES Reference Number	2024.0133
Funder Reference Number:	
This protocol has regard for the HRA guidance and order of content	

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Hempler

Date: 01/08/2024

.....

Name (please print): Francesca Temple-Brown

.....

Position: Research Governance and Facilitation Officer.....

.....

Chief Investigator:

Signature: .....

Date: 5/8/24

Name: (please print): ANITA WALE

.....

KEY STUDY CONTACTS	
Chief Investigator	Dr Anita Wale, Consultant Radiologist, Deputy Research Lead, St George's Hospital
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Sponsor	St George's, University Hospitals NS Foundation Trust Name: Subhir Bed Position: Lead Sponsor Email: researchgovernance@sgul.ac.uk St Georges Joint Research & Enterprise Service (JRES), Cranmer Terrace SW17 ORE
Funder(s)	St George's Hospital NHS Foundation Trust
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Committees	

STUDY SUMMARY	
Study Title	Quantitative assessment of image quality in rectal cancer MR images when using artificial intelligence reconstruction techniques
Internal ref. no. (or short title)	Assessing the use of artificial intelligence in rectal magnetic resonance imaging
Study Design	Observational clinical study

Study Participants	Healthy volunteers and patients referred for rectal MRI at St George's Hospital General Radiology MRI Department
Planned Size of Sample (if applicable)	75
Follow up duration (if applicable)	N/A
Planned Study Period	June 2024 – April 2025
Research Question/Aim(s)	Hypothesis: AI reconstruction techniques can be successfully implemented into the MRI rectal protocol, providing improved image quality and/or reduced acquisition times improving patient outcomes and staff workload.

FUNDING AND SUPPORT	
FUNDER(S)	**This study is unfunded with any resources used in this study volunteered by St George's Hospital's General Radiology MRI department & Medical Physics and Clinical Engineering Department.**

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Steering Groups

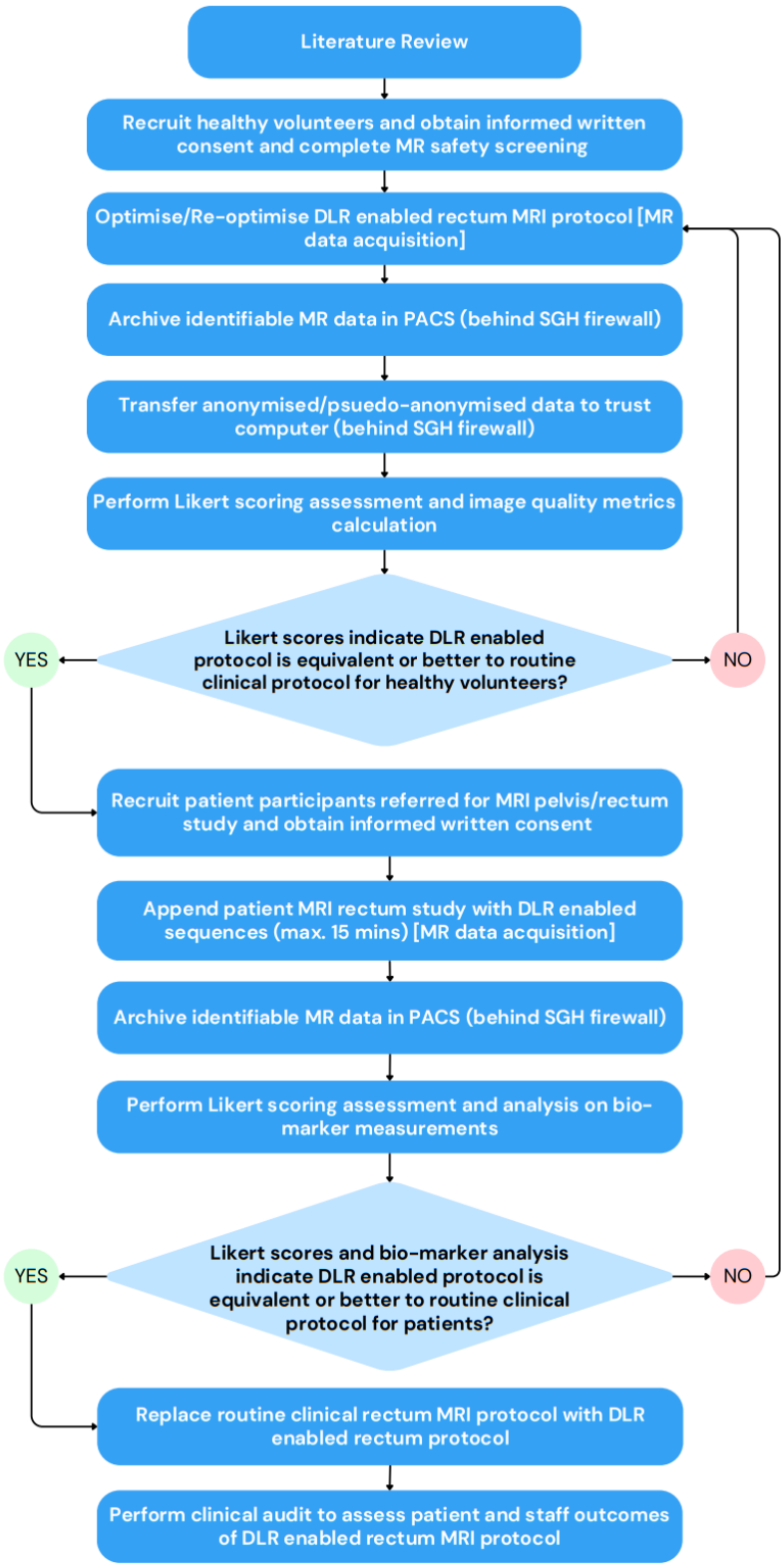
This section details the members of the steering group who are responsible for coordinating and the conduct of this study.

Trial Steering Group	
Chair	**Zach Pang, MRI Physicist**
Member	**Khaliesah Bolhassan, Trainee Clinical Scientist**
Member	**Anita Wale, Dr, Consultant Radiologist**

PROTOCOL CONTRIBUTORS

- The responsibilities of the sponsor is to approve this study and help facilitate the start of this study, which primarily involves helping this study achieve research ethics approval.
- Discussion with service users, including radiologists, have concluded that optimised MRI sequences with AI reconstruction techniques and used on healthy volunteers will need to be reviewed by them before being trialed/appended to clinical studies, which are needed for validation.
- No patients, their carers, nor members of the public have contributed to this study's protocol design.

STUDY Schematic:


Literature Review
Recruit healthy volunteers and obtain informed written consent and complete MR safety screening
Optimise/Re-optimise DLR enabled rectum MRI protocol [MR data acquisition]
Archive identifiable MR data in PACS (behind SGH firewall)
Transfer anonymised/psuedo-anonymised data to trust computer (behind SGH firewall)
Perform Likert scoring assessment and image quality metrics calculation
Likert scores indicate DLR enabled protocol is equivalent or better to routine clinical protocol for healthy volunteers?
YES
NO
Recruit patient participants referred for MRI pelvis/rectum study and obtain informed written consent
Append patient MRI rectum study with DLR enabled sequences (max. 15 mins) [MR data acquisition]
Archive identifiable MR data in PACS (behind SGH firewall)
Perform Likert scoring assessment and analysis on bio-marker measurements
Likert scores and bio-marker analysis indicate DLR enabled protocol is equivalent or better to routine clinical protocol for patients?
YES
NO
Replace routine clinical rectum MRI protocol with DLR enabled rectum protocol
Perform clinical audit to assess patient and staff outcomes of DLR enabled rectum MRI protocol

ABBREVIATIONS	
AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
ISF	Investigator Site File
NHS	National Health Service
NIHR	National Institute for Health Research
PI	Principal Investigator
REC	Research Ethics Committee
SAE	Serious Adverse Event
SGUL	St Georges, University of London
SGH	St Georges, University Hospitals NHS Foundation Trust
JRES	(St Georges) Joint Research and Enterprise Services

STUDY PROTOCOL

Quantitative assessment of image quality in rectal cancer MR images when using artificial intelligence reconstruction techniques

1 BACKGROUND

Aim: This study aims to assess the influence of Deep Learning Reconstruction (DLR) techniques on rectal cancer MR images and the patient pathway. National implementation of DLR techniques was initiated to combat COVID-19 backlogs (GOV.UK, 2023) and can maintain or increase MRI image quality while decreasing acquisition time. While this improves the clinical service by reducing waiting times and increases patient comfort, the use of DLR for rectal cancer imaging is yet unvalidated and must undergo qualitative and quantitative assessment. This is crucial for rectal cancer imaging as tumour size must be accurately determined as this is a biomarker for rectal cancer staging (Horvat et al, 2019).

Literature Review: As a Cancer Centre, St George's University Hospitals NHS Foundation Trust treats patients with colorectal cancer in Southwest London and hosts various screening programs, including that for colorectal cancer (St George's University Hospitals NHS Foundation Trust, n.d.). Colorectal cancer surgery is performed at St George's and among the methods of identifying and staging colorectal cancers include MR imaging (St George's University Hospitals NHS Foundation Trust, n.d.). However, waiting times for patients referred to St George's for treatment for colorectal cancer are currently at 15 weeks (about 3 and a half months), and waiting times for a patient's first outpatient appointment is as high as 16 weeks (My Planned Care NHS, n.d.). Guidance from NHS England state that there should be a maximum of two months (62 days): "From receipt of an urgent GP (or other referrer) referral for urgent suspected cancer or breast symptomatic referral, or urgent screening referral or consultant upgrade to First Definitive Treatment of cancer" (NHS England, 2023). While colorectal cancer is considered a slow-progressing cancer, it was found to be the second highest in cancer-related deaths overall and ranks as the second highest cause of death in men younger than 50 years old in the US (Siegel et al. 2023). Overall survival is closely dependent on early detection: 5-year overall survival is 95-100% for Stage I cancer and drops to 7-8% for stage IV cancer (A.Wale, n.d.).

While various methods of staging rectal cancer exist (pathological staging and contrast-enhanced CT), MRI is crucial for rectal cancer staging. NICE guidelines mandate high-resolution MRI imaging of the rectum in the UK for the identification of metastatic disease (NICE, 2022). Imaging determines the patient pathway and patient treatment based on detectable tumour features visible in MRI (A.Wale, n.d.). Various markers are used by reporters to identify and stage rectal cancer, including the extension of the tumour through the bowel wall, the detection of the circumferential resection margin, detection of extramural vascular invasion, the assessment of nodal status and extranodal tumour deposits, as well as tumour height (A.Wale). MRI is capable of achieving all of these and has the benefit of being non-invasive and does not include exposing the patient to ionising radiation.

While specific protocols naturally vary between hospitals, the current clinical standard for rectal MRI includes a T2-weighted turbo spin echo (TSE) without fat saturation from the aortic bifurcation to the sphincter, with a small field-of-view (FOV) oblique and a large FOV axial and sagittal image as a minimum. This allows for the localisation of the primary tumour (Horvat et al, 2022). Other sequences that could be added include diffusion-weighted imaging (DWI), 3D T2-weighted imaging, contrast-enhanced T1-weighted imaging (Horvat et al, 2019). At St George's, the basic rectum protocol includes a T2w TSE sagittal (for planning), a T2w TSE axial of the whole pelvis, and T2w TSE coronal and axial obliques (with small FOV in the plane of the tumour). Including the localiser, this basic protocol can take over 20 minutes. Further protocols could be added which could provide more diagnostic information for

radiologists (eg. DWI to support localisation, imaging of the nodes to assess cancer spread), however this would cause an increase in scan duration. Long scan times are one of the main drawbacks of MRI in general as patient discomfort, anxiety and claustrophobia can deter patients from being scanned.

In 2023, the UK government rolled out artificial intelligence (AI) tools across the NHS to combat waiting times, which had increased drastically after the peak of the COVID-19 pandemic (GOV.UK, 2023). This included Siemens' Deep Resolve Boost technology, a deep learning image reconstruction (DLR) technology used in MRI (Siemens Healthineers, n.d.). DLR reconstructs MR images from under-sampled k-space data with image quality comparable to that obtained from a fully sampled data set (Lin et al, 2023). To convert raw k-space data to image space, a Fourier transform is performed on k-space data, which contains frequency and phase information. In DLR, the Fourier transform is first performed on zero-filled k-space data to produce an aliased image, then uses training data to map the aliased image to the to the reconstructed image via a convoluted neural network (CNN) (Lin et al, 2023). Because k-space is not sampled completely, this decreases scan time, which benefits the patient experience and increases efficiency of throughput through the MRI department.

In conventional imaging acceleration techniques, there is a known trade-off between acquisition time and signal-to-noise ratio. However, in DLR imaging, noise maps are used which are acquired with the raw data directly into the image reconstruction through iterative techniques, providing clear depiction of fine structures and edges (Magnetom Flash, 2021). DLR denoising techniques allow more effective denoising without increasing scan time.

The combined improvements in scan time and image quality make DLR technology a promising tool to improve patient experience and throughput within the MRI department at St George's, particularly in Rectal MRI where fine soft tissue boundaries and structures play a key role in diagnosis and staging, and decreasing scan time could allow for more sequences to be added to the protocol which can provide more diagnostic information for the reporters and decrease patient recalls.

Although a relatively new technology, studies are emerging on the effectiveness of DLR in MRI not only in decreasing scan time but also in improving image quality. Brix et al. found that in a three-month trial, procuring DLR shortened patient scans allowed the hospital to sustain current MRI service levels with one fewer scanner, enabling a 399,000EUR cost saving annually (Brix et al, 2024). In terms of image quality, Zerunian et al. concluded that signal-to-noise ratio (SNR) and contrast-to-noise ratio (CNS) were both higher in DLR images compared to conventional imaging in a blinded Likert scale assessment scored by radiologists. Furthermore, higher image quality could also be achieved while simultaneously shortening the total protocol scan time from 12:59 minutes to 6:26 minutes (Zerunian et al, 2023).

However, DLR technology cannot be implemented on rectal cancer MRI without thorough validation to assess feasibility. DLR algorithms are known to be a 'black box', where their failure modes are not well understood (Lin et al, 2023). There have also been cases where abnormalities on the fully sampled images have not been visualised on deep learning-reconstructed images (Knoll et al 2020). Therefore, the use of DLR in rectal cancer imaging must be thoroughly validated and feasibility assessed before implementation into the clinical protocol. This will require the participation of volunteers and patients who have been referred for an MRI pelvis scan for a rectum study.

2 RATIONALE

One of the disadvantages in MRI is that acquisition times can be lengthy, making it likely that patient movement whilst in the scanner will affect image quality and making it more difficult for patients to complete their MRI scan (Hollingsworth et al, 2015). In recent years, waiting lists of patients referred for MRI have also been at an all-time-high as a result of the COVID-19 pandemic (GOV.UK, 2023).

To tackle this backlog, manufacturers have developed Artificial Intelligence (AI) image reconstruction (DLR) techniques that compensate for the poor image quality that results when using higher accelerating/parallel imaging factors during MRI scanning (Magnetom Flash, 2021). This also has the potential to improve patient compliance.

These DLR techniques are still relatively new and require a number of resources including radiographer, radiologist and clinical scientist support to optimise the technique. Consequently, implementation across the NHS has been slow and has therefore not yet been validated on rectum MRI protocols. Therefore, the aim of this study is to demonstrate that DLR techniques can be implemented in rectum MRI protocols, as well as provide recommendations for its implementation.

3 THEORETICAL FRAMEWORK

MRI is the gold standard for imaging rectal disease with much discussion in the literature regarding the ideal imaging protocol. The pre-existing clinical rectum MRI protocol at St George's Hospital consists of several T2-weighted Turbo-Spine Echo (TSE) sequences to visualise the primary tumour, the surrounding tissue/organs as well as local nodes. This is in agreement with the literature (Pizzi et al, 2018).

Following the initial imaging, the patient will follow a complex pathway with multiple strategies including neo-adjuvant chemo-radiotherapy, surgery, adjuvant chemo-therapy, watch-and-weight, follow-up imaging or no follow up imaging (A.Wale). The path selected by the clinicians is dependent on the biomarkers measured within the T2-weighted images.

Currently, DLR techniques for the MRI scanners within St George's Hospital's General Radiology department can only be used with Turbo Spin-Echo (TSE) sequences and though it has the potential to reduce acquisition times, it must be validated to ensure it can produce equivalent image quality and bio-marker measurement accuracy. All sequences enabled with DLR techniques will be used in accordance with their CE marking. The assessment will involve radiologists, as suggested by the manufacturer, completing Likert scoring assessments, which are common in projects that assess image quality (Mantiuk et al, 2012).

4 RESEARCH QUESTION/AIM(S)

Aims of the project:

This local validation project aims to explore the use of DLR techniques in clinical rectum MRI studies. This will also involve assessing the outcomes to patients referred for these types of scans, as well as for staff involved in the patient pathway (radiographers and radiologists).

4.1 Objectives

Primary Objectives:

i) Create a DLR enabled MRI Rectum protocol that has equivalent or better image quality as the pre-existing clinical protocol with support from radiographers and radiologists.
ii) Image volunteers using the DLR protocol and iteratively review and re-optimise, if necessary, with radiologist input.
iii) Validate the DLR protocol on clinical MRI rectum studies.

4.2 Outcome

Primary outcome:

To demonstrate non-inferiority of the DLR enabled MRI rectum technique to the current clinical protocol by:

a. Following a reduction in the acquisition time equivalent image quality is achieved (by Likert score – Median likert score DLR enabled >= clinical)

Secondary outcomes:

a. To show agreement between the clinically relevant measurements of rectal tumours on DLR enabled vs clinical scans
b. To describe the potential benefits of using DLR enabled protocols, including shortened acquisition times and improved imaged quality.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Radiographers, radiologists and physicists together will optimise the initial rectum protocol with DLR techniques enabled on healthy volunteers in the initial outset. Images will be pseudo-anonymised/anonymised and stored on the trust's Patient Archiving and Communications System (PACS) by the scanning radiographer. Data that can be used to identify the healthy volunteers will be stored in a locked spreadsheet behind the trust's firewall. This can be used to identify a volunteer whose images contain an incidental finding.

Volunteer images will be viewed on PACS, and a qualitative image quality assessment will be performed using a Likert scoring assessment undertaken by Consultant Radiologist Dr Anita Wale. The Likert scoring form includes scores for image quality (signal-to-noise ratio, overall image quality), and assessment of anatomical features (rectal wall, muscle fibres, intersphincteric plane and myentric plexus) as well as an overall assessment of whether or not the radiologist agrees the image is of adequate quality to report. The likert scale also includes an assessment on bowel motion. These scores will be documented on paper and stored in a locked cabinet in the medical physicists' office (MRI Annexe - ground floor) that is secured with coded pin access. These scores will contain a code to link the scores with the images acquired. No information that can be used to identify the volunteers will be recorded on these documents.

Any images that are accessed in order to perform image quality measurements e.g. SNR, will be done so by MRI physicists (Zach Pang and Khaliesah Bolhassan). The images will be anonymised/pseudo-anonymised and exported from PACS to a trust terminal so that the anonymised/pseudo-anonymised images remain behind the trust firewall. Image quality metrics will also be calculated using an in-house Matlab 2022b script written by MRI physicists (Zach Pang and Khaliesah Bolhassan).

Once a DLR enabled rectum protocol has been established, patients who meet the inclusion criteria will be invited to take part in this study. If they give informed written consent, their routine scans will be appended with the DLR sequences. A maximum of 15 mins of sequences will be added. Their participation in this study will be noted on the trust's Radiology Information System (RIS)/Soliton. Further detail relating to the inclusion and exclusion criteria for participants can be found in section 7 of this study protocol.

Acquired images will be archived to PACS by the scanning radiographer and will undergo qualitative assessment, the same Likert scoring employed with the healthy volunteers, by Dr Anita Wale. Again, these scores will be documented on paper and stored in a locked cabinet in the medical physicists'

office that is secured with coded pin access. These scores will contain a code to link the scores with the images acquired. No information that can be used to identify the patients will be recorded on these documents. Statistical analysis of the Likert scores will be carried out using a two-tailed pairwise Wilcoxon signed-rank test.

Additionally, bio-marker measurements will also be carried out by the reporting radiologist with statistical analysis of the bio-marker measurements between the pre-existing and DLR enabled sequence for the patient sample group also performed by the MRI physicists (Zach Pang and Khaliesah Bolhassan).

Conclusions regarding image quality and the validity of DLR being suitable for clinical rectum protocols will be made by Dr Anita Wale, Zach Pang and Khaliesah Bolhassan.

Any other hard copies of data/notes will be stored in the locked cabinet within the locked medical physicists' office.

6 STUDY SETTING

This is a single centre study at St George's Hospital with three MRI scanners that each have up-to-date software versions with DLR functionality. Healthy volunteers will be recruited for initial optimisation of the DLR enabled rectum protocol and will be recruited from within St George's Hospital's Medical Physics and Clinical Engineering (MPCE) group via an email on the joint mail base.

It will be explained to volunteers that images will be reviewed in the context of image quality assessment. In the event of an incidental finding, the volunteer's GP will be notified. A volunteer will not be scanned if they do not provide details of their GP, NHS number, and do not give consent to being scanned. Any volunteer that is vulnerable, not an adult, is/may be pregnant or has any other contraindications to MRI will be immediately excluded from this study. All volunteer images will be stored on PACS and accessed only by Anita Wale, Zach Pang, Khaliesah Bolhassan or any other delegate listed on the delegation log. These images will be stored for up to 10 years following completion of the study, unless a participant wishes for them to be deleted at an earlier date.

Validation will need to be carried out on adult patients referred to St George's Hospital's General Radiology MRI department for an MRI pelvis scan for a rectum study. This research setting is appropriate since there are approximately 200 patients who are referred for a pelvis MRI each year, with patients also having follow-up scans throughout their care.

Potential participants will be identified by the Radiology Information System (RIS) and their suitability will be assessed. Any patient that is vulnerable, not an adult, is/may be pregnant or has any other contraindications to MRI will be immediately excluded from this study.

Once a patient's suitability has been approved, they will be invited to take part by post and a participant information sheet (PIS) will be provided (e.g. in person, via email or post). The potential participant will be provided with the contact details of the researchers (Zach Pang and Khaliesah Bolhassan) if they have any questions.

If the patient wishes to participate in this study, they will be provided with the PIS and given another opportunity to read it and ask questions on the day of their scan before written consent is obtained. This consent will be recorded on RIS/Soliton. The participant will then continue through the safety checks, which will be the same process as their referred scan (MRI screening questionnaire and changing into patient gowns). These will be performed by St George's Hospital MRI radiographers.

Participants will be setup by the radiographers and have the same patient setup as the routine pelvis MRI. This will include being placed in the MRI scanner (Siemens Magnetom Sola 1.5T or Siemens Magnetom Vida 3T) either in head-first-supine or feet-first-supine position with a single, multi-channel anterior receiver coil and the built in spine coil activated. Participants will also spend up to an additional 15 minutes of scanning due to the DLR enabled sequences being appended to the study.

All scanning will be carried out by the scanning radiographer. Contrast will never be given as part of this protocol. Participants will have no further responsibility in this study once their scan is complete.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

This section sets out with precise definitions of which participants are eligible for this study, defining both inclusion and exclusion criteria.

7.1.1 Inclusion criteria

Staff in the Medical Physics and Engineering group, plus adult patients that have been referred to St George's Hospital General Radiology MRI department for an MRI pelvis study and able to withstand up to an additional 15 minutes in the MRI scanner will be considered for participation in this study.

The ability for volunteers and patients participating in this study will not be dependent on:

- Gender.
- Ethnicity.
- Socio economic grouping.
- Clinical condition.
- Location.

7.1.2 Exclusion criteria

Any volunteer that is not an adult; and is/or may be pregnant, will be excluded from this study.

Any patient that cannot give informed written consent, cannot complete a screening questionnaire, is not an adult; has not been referred for an MRI pelvis scan for a rectum study at St George's Hospital General Radiology MRI department as an outpatient; is an at-risk patient; and is/or may be pregnant, will be excluded from this study.

Non-English speakers will be excluded from this study as informed consent cannot be guaranteed and questions the participants may have may not be satisfactorily answered.

7.2 Sampling

7.2.1 Size of sample

We aim to recruit a maximum of **75** participants in this study, which includes **15** healthy volunteers and **60** patient participants (see GPower calculation below).

GPower 3.1.9.7 was used to undertake a power analysis calculation by selecting a Wilcoxon signed-rank test (matched pairs), with the following inputs:

- Two tails
- Normal distribution
- Large effect size (dz) of 0.8
- A error probability of 0.05
- Power (1-β error probability) of 0.95

This results in a sample size of **24**.

However, the actual number of patient participants required will be different to the sample size calculated by GPower as it is dependent on how effective DLR techniques are at reducing acquisition times.

A conservative estimate for the reduction in the total acquisition time is approximately 50%. Since the routine protocol is 23 minutes and 57 seconds, decreasing the acquisition time by 50%, and considering only the sequences that can have DLR techniques enabled, results in a DLR enabled protocol of 11 minutes and 46 seconds.

However, as the rectum MRI booking slot is a maximum of 30 minutes, the routine and DLR enabled protocol, which combined is 35 minutes and 43 seconds, cannot be acquired in one booking slot. **Therefore, the first half of the DLR enabled protocol will need to be appended to 24 patient participant scans and the second half of the DRL enabled protocol will need to be appended to another 24 patient scans. Increasing or exceeding the minute booking slot cannot be exceed (as stipulated by Mr Terence McGuckin (Superintendent of General Radiology MRI).**

Additionally, patient participants may drop out of the study, whilst other patients may have to be excluded following their scan. An example of the latter may be that the patient had significant movement in the DLR enabled scan, which did not occur during the routine part of the scan. This dropout rate is estimated to be **20%**, as indicated by Mr Terence McGuckin (Superintendent of General Radiology MRI).

The need to double the number of participants due to logistical factors related to the booking slot, a dropout rate of 20%, as well as the need to scan approximately 3 volunteers results in an estimated maximum sample size of 75 participants:

((24 × 2) ÷ (1 – 20%)) + 15 = 75 participants.

7.2.2 Sampling technique

This study will use the convenience sampling technique due to the ease of inviting/recruiting patient participants that have been referred for an pelvis MRI for a rectum study. It is expected that there will not be any bias from this sampling technique that would cause the sample results to be skewed from the patient group population.

7.3 Recruitment

This section details the participant eligibility screening process for this study and includes the methods used to identifying eligible participants/sample.

7.3.1 Participant identification

Healthy volunteers are needed initially to optimise a rectum protocol enabled with DLR. Members of the MPCE group at St George's Hospital will be invited to volunteer in this study via an email to the joint MPCE mail base by Zach Pang or Khaliesah Bolhassan. If a volunteer is suitable for participating,

they will be provided with a PIS that details the purpose and their role in the study. If volunteers wish to proceed, they must provide details of their GP, NHS number, and complete a written consent form a volunteer screening form.

A list of healthy volunteers from the MPCE group that wish to participate in this study will be maintained and include their full name, work email address, when they were last screened and if they have provided written consent. This will be maintained by Zach Pang and Khaliesah Bolhassan. Any volunteers that fail to meet the inclusion criteria or meet any exclusion criteria will not be included in this study.

Validating the DLR technique requires imaging patients with or suspected of having rectal cancer, who will be identified using the trust's RIS. This will be carried out by Anita Wale, Zach Pang and/or Khaliesah Bolhassan who will search on RIS for patients referred for a pelvis MRI for a rectum study. If suitable patients are identified, they will be invited to take part in the study and provided with a PIS through the post with ample time to read the information and consult family members/friends/legal representatives. If the patient wishes to proceed with participating in the study, informed written consent will be obtained and noted on Soliton. This invitation will be sent by Zach Pang or Khaliesah Bolhassan.

A list of patients approached to participate in this study will be maintained to ensure their eligibility onto the study has been checked and recorded, and to avoid inviting a patient who had previously turned down the study invitation.

7.3.2 Consent

The participant will receive an invitation to the study, as well as a PIS that clearly explains their participation in the study is completely voluntary, they have the right to withdraw from the study at any time, and their responsibility whilst on the study. The participant will be provided with the PIS at least 24 hours before the scan so that they have enough time to read the PIS in its entirety and contact the researchers if they have any follow-up questions. This will also be reiterated to the participant on the day of their scan.

The PIS will ensure that the patient:

- Understands the purpose of the study.
- Understands their responsibility whilst participating in the study.
- Understands the benefits, risks and burdens of their participation in the study.
- Understands that they may withdraw from the study at any time without the need to give a reason for doing so.
- Understands that they do not have to participate in the study and that their care will not be affected.
- Understands that the MR images collected in this study will be stored on St George's Hospital's computer network/PACS and that their medical history/results related to their MRI may need to be accessed.
- Understands that their MR images may be used in a scientific publication and that these will not contain any images that can be used to identify them.

Once the participant has reviewed the PIS and understood the points above, then informed written consent will be obtained from the participant.

Consent provisions for collection and use of participant data and biological specimens

No biological specimens will be taken as part of this study. The data that concerns the healthy volunteers from the MPCE group will include their full name, date of birth, NHS number, GP, height and weight. Additionally, their images will be stored on the Trust's PACS system.

Patient participants will also have the same details stored/accessed; however, this information is accessed as part of their care and so no additional patient identifying information is accessed that would not have been otherwise.

If a patient participant wishes to withdraw from the study, permission will be sought to use any images acquired up till that point. If permission by the patient is denied, their information will not be accessed and their images will not be used in the study.

7.3.3 **Data collection tool**

Case Report Forms will be designed by the CI and or PI.

- On paper CRFs all data should be entered legibly in black ink. If the Investigator makes an error, it will be crossed through with a single line in such a way to ensure that the original entry can still be read. The correct entry will then be clearly inserted. The amendment will be initialled and dated by the person making the correction immediately. Overwriting or use of correction fluid will not be permitted.

The Staff Delegation of Responsibilities Log should identify all trial personnel responsible for data collection, entry, handling and managing the database.

Data that will be recorded directly into the CRF and contain:

- Patient details (name, DOB, NHS number and/or MRN)
- Confirmation of their eligibility including date
- Study ID
- Written consent form signed by the participant
- Signed notes made by the investigator with time and date recorded
- Withdrawal form (if necessary) with date and time recorded.

This study will not handle any biological samples. However, information recorded in patients' history/medical records may be accessed that includes prior imaging and prior medical procedures.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Potential Benefits

As stated in the PIS, the benefit to taking part in the study may be that the additional imaging performed may provide additional information to the radiologist that was not available in the clinical protocol. This is at the expense of spending up to an additional 15 minutes inside the scanner.

Furthermore, the PIS also reiterates that the information gathered in the study will help implement a protocol with DLR techniques aimed at reducing acquisition times and/or improving image quality.

This study will be performed according to the Declaration of Helsinki (1964) and with the approval from the local Research Ethics Committee (REC) before commencement of the study. Throughout this study, confidentiality will be maintained for both volunteer and patient alike, in accordance with the Data Protection Act (2018). For patients specifically, no additional information will be accessed that would not have been accessed as part of their routine rectum MRI scan/care.

8.2 Assessment and management of risk

There are no adverse events anticipated as part of this study as radiographers are specifically trained to screen patients and conduct MRI scans that minimise the risk of projectile effects, effects to implants, patient heating, acoustic noise and other bio-effects. The risks of these occurring during the study is no different to the routine clinical protocol that the patient was referred for. Additionally, Gadolinium-Based Contrast Agents (GBCAs) will not be given as part of the routine or study protocol. All risk assessments regarding the clinical use of MRI are stored locally within the MRI department.

To minimise the risk of safeguarding issues, patient participants will only be deemed suitable for participating in this study if they are not ‘at-risk patients’ and do not have any safeguarding alerts on the Hospital Information System (HIS). Any safeguarding issues that may arise will be dealt with according to the Trust’s safeguarding policy. All researchers and members on the delegation log will have up-to-date safeguarding training, which is required by the trust and ensured via Mandatory and Statutory Training (MAST).

<u>COVID-19 Risk Assessment and Management Strategy</u>

All staff employed by SGUL and/or SGH NHS Foundation Trust are required to complete an ongoing COVID-19 risk assessment prior to undertaking any work on site, which includes research activity. This process is continuously monitored by the responsible line manager.

Participants (unaffected or affected) will not be recruited if they are deemed high risk or are in close contact with someone at risk. The Research Team will contact research participants ahead of scheduled study visits on-site to check for COVID-19 symptoms and the symptom check will be repeated when patients attend the hospital site for the study visit.

Participants will receive information regarding the extra precautions that will be taken in light of the COVID-19 pandemic in the Patient Information Sheet. This will detail steps that patients should take if they have concerns about exposure to COVID-19 through participating in the research, or believe that they are symptomatic or have been in close contact with another person believed to be symptomatic. The Patient Information Sheet will also have contact details for the Research Team for patients to get in touch if they have any concerns or queries about this.

All research personnel are expected to comply with the NHS Trust and University policies on COVID-19.

All patients attending the hospital site for research visits and/or routine clinical follow-up will be expected to abide by the NHS Trust and University policies on COVID-19 which include wearing

suitable PPE (provided by the NHS Trust on arrival), adhering to the visitor policy on social distancing and following the one-way routing systems whilst on site.

The schedule of study assessments has been designed so that they align with the current routine clinical pathway for this patient population

Therefore, research participants and site staff are not perceived to be at any additional risk of exposure to COVID-19 through participation in this research study.

8.3 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from an appropriate REC for the study protocol, informed consent forms, participant information sheets and other relevant documents.

For HRA- NHS REC reviewed research

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- It is the Chief Investigator's responsibility to produce the annual reports and submit the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- The Chief Investigator will notify the REC of the end of the study within one year after the end of the study.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

Regulatory Review & Compliance

Before any patients are enrolled onto the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

Amendments

If amendments to the study are needed, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

8.4 Peer review

Aim: This section describes the peer review process required for approval by the sponsor.

This protocol has been peer reviewed by an independent expert and their comments are attached in appendix 4. Their contact details are as follows:

Mike Mills, MRI Physicist, mmills@sgul.ac.uk

A peer review form has also been completed and can be found in Appendix 5.

8.5 Patient & Public Involvement

Patients will participate in this research project as study subjects that involves undergoing additional scans that have been appended to their routine clinical scan.

Carers and other members of the public may also be involved if they are to assist a patient with deciding whether or not to take part in the study. This may also involve them reading the participant information sheet and posing additional questions to researchers.

Patients, carers and other members of the public are not expected to assist in any other areas of the research study.

8.6 Protocol compliance

Protocol deviations, non-compliances, or breaches are departures from the approved protocol.

All protocol deviations must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

8.7 Data protection and patient confidentiality

All data will be handled in accordance with the Data Protection Act 2018 (UK implementation of the EU General Data Protection Regulation (GDPR)).

Any Case Report Forms (CRFs) will not bear the participant's name or other directly identifiable data. The participant's trial Identification Number (ID) only, will be used for identification. The Subject ID log can be used to cross reference participant's identifiable information.

8.8 Indemnity

St George's University Hospitals NHS Foundation Trust sponsored research:

St Georges University Hospitals NHS Foundation Trust is party to NHS Litigation Authority (NHSLA) / NHS Resolution. As an NHS body it is liable for clinical negligence and other negligent harm to individuals covered by their duty of care. NHS Institutions employing researchers are liable for negligent harm caused by the design of studies they initiate.

8.9 Access to the final study dataset

As this is a single centre study, the full dataset will only be handled by study investigators at St George's Hospital. No personal patient data will be shared with other organisations and no directly identifiable patient data will be shown on the dataset.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

Publication: "Any activity that discloses, outside of the circle of trial investigators, any final or interim data or results of the Trial, or any details of the Trial methodology that have not been made public by the Sponsor including, for example, presentations at symposia, national or regional professional meetings, publications in journals, theses or dissertations."

All scientific contributors to the Trial have a responsibility to ensure that results of scientific interest arising from Trial are appropriately published and disseminated. The Sponsor has a firm commitment to publish the results of the Trial in a transparent and unbiased manner without consideration for commercial objectives.

To maximise the impact and scientific validity of the Trial, data shall be consolidated over the duration of the trial, reviewed internally among all investigators and not be submitted for publication prematurely. Lead in any publications arising from the Trial shall lie with the Sponsor in the first instance.

Before the official completion of the Trial,

All publications during this period are subject to permission by the Sponsor. If an investigator wishes to publish a sub-set of data without permission by the Sponsor during this period, the **Steering Committee/the Funder** shall have the final say.

Exempt from this requirement are student theses that can be submitted for confidential evaluation but are subject to embargo for a period not shorter than the anticipated remaining duration of the trial.

Up to 180 days after the official completion of the Trial

During this period the Chief Investigator shall liaise with all investigators and strive to consolidate data and results and submit a manuscript for peer-review with a view to publication in a reputable academic journal or similar outlet as the Main Publication.

- The Chief Investigator shall be senior and corresponding author of the Main Publication.
- Insofar as compatible with the policies of the publication outlet and good academic practice, the other Investigators shall be listed in alphabetic order.
- Providers of analytical or technical services shall be acknowledged, but will only be listed as co-authors if their services were provided in a non-routine manner as part of a scientific collaboration.
- Members of the Steering Group shall only be acknowledged as co-authors if they contributed in other capacities as well.
- If there are disagreements about the substance, content, style, conclusions, or author list of the Main Publication, the Chief Investigator shall ask the Steering Group to arbitrate.

Beyond 180 days after the official completion of the Trial

After the Main Publication or after 180 days from Trial end date any Investigator or group of investigators may prepare further publications. In order to ensure that the Sponsor will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor for review at least sixty (60) days prior to submission for publication, public dissemination, or review by a publication committee. Sponsor's reasonable comments shall be reflected. All publications related to the Trial shall credit the Chief and Co-Investigators as co-authors where this would be in accordance with normal academic practice and shall acknowledge the Sponsor and the Funders.

9.2 Archiving Arrangements

Each site will be responsible for their onsite level study archiving. The trial essential TMF along with any central trial database will be archived in accordance with the sponsor SOP.

10 REFERENCES

List the literature and data that are relevant to the study, and that provide background for the study. Please ensure the text contains appropriate cross references to this list.

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11. APPENDICIES

11.1 Appendix 1

Below is a table for the schedule of procedures.

Procedures	**Visits**		
	Booking (over the phone)	**Scan Date**	**Post Scan Date**
Informed consent	x		
Screening	x		
Medical history	x		
Observation of Scan		x	
Analysis			x

11.2 Appendix 2

Amendment Log				
Amendment No.	**Protocol version no.**	**Date issued**	**Author(s) of changes**	**Details of changes made**
1	0.2	N/A	Zach Pang	Changes made to protocol study following feedback from peer reviewer (Mike Mills).

11.3 Appendix 3

Complete the form below. It will require review and sign-off by the Institute Director (SGUL) or the Care Group Lead (SGHFT).

Research Data Protection Impact Assessment (DPIA)

Data Protection Impact Assessments (DPIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations under the Data Protection Act 2018 (DPA 18) and meet individuals' expectations of privacy.

A DPIA helps identify data privacy risks when planning new, or revising existing, projects and to identify actions to mitigate these risks. In the rare cases where risks cannot be mitigated at all it may be necessary to consult with the Information Commissioner's Office (ICO). Under data protection legislation it is a legal requirement to complete a DPIA in the following circumstances:

- • where data processing is likely to result in a high risk of harm to individuals, e.g. new, invasive technology is proposed
- • when large volumes of personal data are processed, e.g. use of behavioural profiles based on website usage
- • when processing special category personal data on a large scale, e.g. healthcare data, genetic tests to assess and predict the disease/health risks

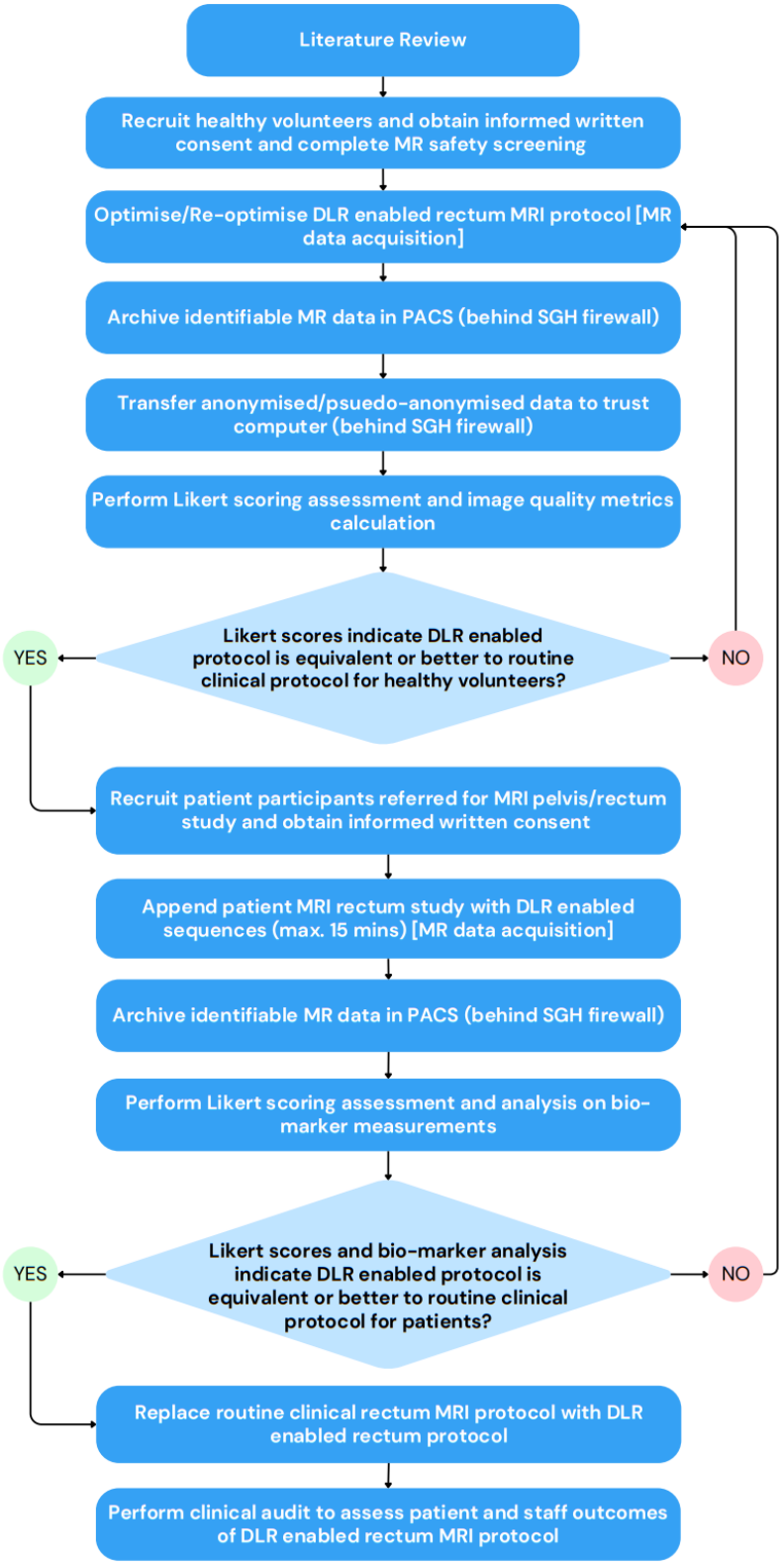
• where publicly accessible areas are monitored, e.g. CCTV or when filming public areas

Therefore a DPIA will be carried out for both internal and partnership projects which require the collection/processing of personal data in any format for the purpose of research.

The DPIA should be carried out towards the start of the project, in order to identify any associated information risks and mitigate in the early stages, before you start processing.

Study Title/Acronym:	Assessing the use of artificial intelligence in rectal magnetic resonance imaging.
JRES Reference Number:	2024.0133
Chief Investigator Name:	Dr Anita Wale
Chief Investigator Email Address:	Anita.wale@stgeorges.nhs.uk

PROJECT DETAILS
Project / process description: **- include / attach processing operations (include a flow diagram or another way of explaining data flows), the purpose and, where applicable, what St George's lawful basis is for the processing of the information.**



What personal data do you intend to use, and why? (List all categories)

As part of the informed written consent procedure, we intend to record every healthy volunteer's full name, date of birth, NHS number and GP address so that a clinically significant incidental finding can be dealt with appropriately if found.

These details are also recorded for patients as part of their routine care.

The volunteer and patient participants' height and weight will also be recorded as these are required to calculate and limit the Specific Absorption Rate (SAR) – an MR safety metric that indicates the likely amount of heating a patient/volunteer will be subjected to due to MRI scanning.

This information may be used to identify and access a patient's medical history as part of this study.

Will the personal data be identifiable, pseudonymised or anonymised (if a mix tick accordingly)		
Identifiable	✓	
*Pseudonymised	✓	
Anonymised		

**Confirm that the key to this data is kept securely away from the used data with strict controlled access*

List all organisations / agencies which will have access to the personal data collection used for this project / process

Only study delegates (listed on the delegation log) at St George's Hospital will have access to the personal data collection used for this project.

Length of the study – include an assessment of the necessity and proportionality of the processing in relation to the purpose. Also include who, internally & externally, has been consulted in the preparation of this DPIA.

As a minimum until 1st of April 2025, or until sufficient data points (75) have been acquired.

If external organisations / agencies are involved, is there a contract or information sharing agreement in place with suitable clauses for data protection and data incident reporting,? If not why not?

No external organisations or agencies are in this study.

RISK			
Can you achieve your objectives using anonymised data? – see ICO Code of Practice on Anonymisation			
Yes	✓		
No		Why not?	
What are the benefits to the individual of their personal data being used for this purpose?			
There would be no difference in medical care between a patient whose patient data has been used for the study and a routine patient not involved in the study. The patient would be contributing to a study which could improve the rectal MRI service at St George's which would benefit them for any future scan.			
What are the organisational benefits of the individual's personal data being used for this purpose?			
Improvement of the rectum MRI service at St George's in the form of improved scan times or image quality.			
What are potential negative impacts to the individual of their personal data being used for this purpose in the event of a Data Breach occurring?			
No additional patient data than would normally be acquired clinically would be obtained for the study. Potential negative impacts are the same that would be experienced as a routine clinical patient.			
How will you avoid causing unwarranted or substantial damage/distress to the individual when using their personal data for this purpose?			
It will be explained to healthy volunteers that their details will be stored behind the trust's firewall or in a secure location. Patient participants will be told that their information will also be secured behind the trust's firewall and that only information/data related to their MRI scan and/or referral for that scan will be accessed.			
Is the data already held by St George's?			
Yes	✓		

No			
Is it held by one of the partner organisations / agencies involved in this process/project?			
Yes			
No	✓	Which agency will be collecting the data	
Have you told the individuals whose personal data you want to use for this purpose, how and why you intend to use their data?			
Yes			
No	✓		
If not, are you intending to tell them?			
Yes	✓		
No		Why not?	
Do you already have the individual's consent to use their data for this purpose?			
Yes			
No	✓	Why not?	Study has not commenced
If not, are you going to ask for their permission?			
Yes	✓		
No		Why not?	
Have individuals been given the opportunity to refuse us permission to use their data for this purpose?			
Yes	✓	Opportunity is given during patient consenting and after initiation of patient withdrawal from study.	
No			

How will you make sure that the personal data you are using is kept accurate and up to date?

Any patient data used for the study will be accurate at the time the scan was acquired. All patient information will be acquired from patient medical records or directly from the patient. If possible, these will be cross-checked.

What steps or controls are you taking to minimise risks to privacy?
Please tick those which apply and provide details of how each is ensured

1. Risks to individual privacy are minimal 2. Personal data is pseudonymised 3. Encryption used in transfers of patient data. 4. Information compliance training for staff has been completed - data protection, information security, FOI 5. Adherence to privacy by design principles 6. Special category personal data is not used 7. Participants opt out at any stage of the research 8. Personal data kept in the UK 9. Research is not used to make decisions directly affecting individuals 10. Short retention limits 11. Restricted access controls	1. Information is only accessed by study delegates. 2. Images transferred from PACS can be pseudo-anonymised and stored in trust PCs. This will be enabled when images are transferred. 3. All staff with access to patient and volunteer participant information access have up to date information governance MAST training 4. The radiographers/radiologists involved with the additional scans are the same staff members who perform the routine clinical scan already undergone by the patient. 5. CRF will be coded so that it does not include patient information. 6. Special category personal data will not be collected or included for the study. 7. Contact details and guidance on how to opt out is included on the Patient Information Sheet (PIS), as well as a withdrawal form. 8. Only anonymised MR images would be shared outside of the trust, eg for publication. No patient identifying information will be shared outside of the trust. 9. Research protocols are only assessed alongside routine clinical scans by reporters, not replacing clinical scans. Any clinical decision made for the patient will be made on clinical scans. 10. All data will be stored on password locked staff computers and only accessible by study delegates.

	11. No patient data would be stored without reason for doing so and deleted once it has been used.

How long will you need to hold the personal data for after the study has completed?

For as long as they are needed for analysis, once data analysis is complete patients' personal information will no longer be useful and will therefore be deleted.

How will you make sure that you are holding data for the appropriate length of time and no longer?

Once the minimum deadline of 1st April 2025 is reached, an assessment of how much data analysis has been completed can be done. Once all 75 datapoints have been acquired and all analysis is done, the patients' personal data can be deleted.

How will the data be held /stored?

All data will be stored on either CRFs or paper copies stored in a locked cupboard in a pin-access office only accessible by members of staff.

Will you be using any electronic and/or paper Case Report Forms (CRFs) to collect data? If so what are these and how will they be held securely and managed at the end of the project?

Yes. CRFs will not bear the participants name or other directly identifiable data. The participants trial ID only will be used for identification and a subject ID log can be used to cross reference participant's identifiable information. The subject ID log will be stored on the Trust's network (behind the firewall) and will be password protected so that only study delegates have access.

Will personal data be transferred/shared between the organisations involved in this project? If so how?

This is a single-site study so patients' personal data will not be shared between organisations.

Will you be transferring personal data to a country or territory outside of the UK? *If yes, name countries and receiving parties.*

Yes – within EEA		
Yes – outside of EEA		
No	✓	

How will you ensure that third parties will comply with data protection obligations?

This is a single site study and no third parties will have access to patient personal information.

What measures are in place to ensure only appropriate and authorised access to and use of, personal data?

Only data relevant to the study will be collected, including participant hospital number, and height and weight (for calculation of SAR). Only study investigators will have access to the data, which will be pseudonymised and stored on password-protected computers within the trust. Any physical documents with participant information will be stored in a locked cupboard in an office only accessible by members of staff with pin access.

How will technical and organisational security be monitored/audited?

Passwords at St George's Hospital are changed regularly as trust policy. All documents with participant personal information are encrypted and only accessible by study investigators.

Declaration

I confirm that the information recorded on this form is, to the best of my knowledge, an accurate and complete assessment of the potential privacy impacts of this study.

Name: Zach Pang

Signature: 

Date: 03/06/2024

Institute Director (SGUL) or Care Group Lead (SGHFT)

Name:

Signature:

Date:

JRES Reviewer

Name:

Signature:

Date:

11.4 Appendix 4

Feedback From Peer Reviewer Related to Study Protocol Version 0.1

Section Feedback Relates To:	Peer Reviewer's Comments:	Corrective Action Taken:

Study Schematic Workflow Diagram (pg 8 & 24)	Peer reviewer has commented: 'I realise this is pedantry, but in your decision statements surely it should be '*at least equivalent'*, or "no worse". You don't need to re-optimise if it is better'.	Changed wording to now state *'Likert scores indicate DLR enabled protocol is equivalent or better to routine clinical protocol for healthy volunteers'* & *'Likert scores and bio-marker analysis indicate DLR enabled protocol is equivalent or better to routine clinical protocol for healthy volunteers'*
Abbreviations	Peer reviewer has commented: 'You use SGH in the schematic'.	We have removed 'SGHFT' from document and replaced with 'SGH'
4.1 Objectives	Peer reviewer has suggested to include '*or better'* when referring to equivalent image quality in the first primary objective.	Wording has been changed to: *'Create a DLR enabled MRI Rectum protocol that has equivalent or better image quality as the pre-existing clinical protocol with support from radiographers and radiologists'*.
5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS	Peer Reviewer has commented: *'Are you going to use the volunteers real details or pseudonymise them at the point of recruitment (so their real details aren't on PACS in an identifiable way)?'*	We have changed the methodology and wording to: *'Images will be pseudo-anonymised/anonymised and stored on the trust's Patient Archiving and Communications System (PACS) by the scanning radiographer'*.
7.2.1 Size of sample	Peer Reviewer has commented: The order of these three sentences is a little jumbled. I can follow it. but you might want to rephrase to something like "We aim to recruit a maximum of 75 participants in this study (see power calculations below), including approximately 3 healthy volunteers from the MPCE group.	Section has been rephrased so that is less 'jumbled' and clearer.

	GPower 3.1.9.7 was used to undertake a power analysis calculation by selecting a Wilcoxon signed-rank test (matched pairs), with the following inputs…."	

11.5 Appendix 5

Peer Reviewer Feedback Form

Project Reference (IRAS/JRES):	2024.0133
Title of project	Quantitative assessment of image quality in rectal cancer MR images when using artificial intelligence reconstruction techniques
Name of reviewer	Mike Mills
Date of review	10/06/2024
Place of work	St Georges, University of London
Post held	MRI Senior Physics Researcher
Purpose of review	Providing feedback and advice regarding the design of the proposed study.
Please rate your suitability to review this study – relevant expertise/skills (score from 10, where 1 is lowest).	9

Please declare any conflicts of interest that may affect your ability to provide an objective review	
I have worked alongside the researchers named in this project prior, however this does not affect my ability to provide an objective review.	

Grading

1. Unable to assess
2. Requires major revision
3. Some areas that should be addressed
4. Minor revisions suggested
5. Clear appropriate

REVIEW CRITERIA	**HINTS**	**COMMENTS**	**Grade 1 low-5 high**
1. Relative merit of the research/importance	• Research aims clear • Research question clear • Addresses a health issue that is important for health and/or society. • Aims, research questions and hypotheses build on and address gaps in existing knowledge. • Public involvement • Relevance to stakeholders	The project is timely and well thought out. AI tools are becoming more a part of the radiology landscape, but thorough validation should be performed prior to implementation to ensure the risk of a loss in diagnostic potential from the images is minimised.	5

		PPIE is not seen as necessary, and I concur with this given the size and scope of the proposed research. No patient facing documentation was presented for review (e.g. patient information sheet or consent forms) and so have not been commented on.	
2. Research quality	• Suitability of study design/methodology for question • Robustness of the methods used. • Includes a description of sample recruitment and proposed methods of data analysis. • Risk of bias, transferability considered as applicable	The methodology is suitable and feasible and addresses both qualitative and quantitative aspects of the implantation of deep learned based reconstruction techniques. Few healthy controls are to be recruited, and from the local department, so there is a small risk that these will not well match the patient population and hence bias the results. However, implementation of the technique in patients follows this initial optimisation/validation in controls, so will be independently assessed.	4
3. Feasibility of the research	• Overall strategy, methodology and analyses are well reasoned and appropriate to achieve the specific aims of the project. • Likely to improve scientific knowledge, concepts, technical capacity or methods in the research field, or of contributing to better treatments, services, health outcomes or preventive interventions. • Achievable within the specified timeframe • Researcher/research team has the appropriate experience and expertise	The methodology is clear, achievable, and appropriate. The team are also more than sufficiently qualified to undertake the proposed research.	5

4. Presentation of the application	• Appropriate overall presentation, including structure, 'understandability', clarity and readability • In general the way in which the application reads and gets the message across reflects well planned and conceived research.	Generally, very clear. A small alteration has been suggested to make the sample size section easier to comprehend has been made.	4
5. Ethical issues (application will have separate ethical review)	• any potential adverse consequences for humans, animals or the environment and whether these risks have been addressed satisfactorily in the proposal	The potential adverse consequences are well laid-out, and it is made clear that for the vast majority of participants (i.e. patients) there is no alteration in risk as the additional sequences simply append a clinical scan.	4
6. Other comments	Any reviewer observations that are not covered in the points above	I would consider anonymising/pseudonymising healthy control participants prior to imaging so no unnecessarily identifiable information/images are retained on the PACS system. Perhaps consider pseudonymising, with a pseudonymisation key only accessible to the research team. I appreciate this may be considered too onerous given the small (n=3) number of healthy controls.	

Overall Score:

Taking into account your ratings summary above, and the comments you have provided, please give an overall score, using the guide below to help you.

Overall Score

A – I recommend acceptance of this project/protocol

Guide

Ranking	Meaning
A	Acceptance
B	Revision and Review
C	Rejection

Signature: M Mills

Date: 10/06/2024