# PROTOCOL

## Surgical Site Infections in Major Lower Limb Amputation – Transmetatarsal Extension: An International Multicentre Audit (SIMBA-T)

SIMBA-T

**Protocol version 1.0, June 2024**

VERN Vascular and Endovascular Research Network

BiCOPS Birmingham Centre for Observational and Prospective Studies

## 1. Protocol changes

| PROTOCOL CHANGES | | |
|---|---|---|
| **Date of change** | **Protocol version number** | **Summary of change** |

## 2. Abbreviations

| | |
|---|---|
| AKI | Acute Kidney Injury |
| BiCOPS | Birmingham Centre for Observational and Prospective Studies |
| CDC | The Centres for Disease control and Prevention |
| DCT | Data Collection Tool |
| IT | Information Technology |
| MLLA | Major Lower Limb Amputation |
| PL | Project Lead |
| SIMBA | Surgical Site Infections in Major Lower Limb Amputation |
| SMG | Study Management Group |
| SSI | Surgical Site Infection |
| TMA | Transmetatarsal Amputation |

## 3. Study Management Group (alphabetical order)

- Lakna Harindi Alawattegama, Vascular Trainee, Black Country Vascular Network
- Nina Al-Saadi, Vascular Trainee, Black Country Vascular Network
- David Bosanquet, Consultant Vascular Surgeon, South East Wales Vascular Network
- Ian Chetter, Professor of Vascular Surgery, Hull York Medical School
- Ismay Fabre, Core Surgical Trainee, South East Wales Vascular Network
- Andrew Garnham, Consultant Vascular Surgeon, Black Country Vascular Network
- Brenig Gwilym, Vascular Trainee, Aneurin Bevan Health Board
- Louise Hitchman, NIHR Doctoral Research Fellow, Hull University Teaching Hospitals
- Judith Long, Vascular Research Manager, Hull University Teaching Hospitals
- Laura Magill, Associate Professor of Clinical Trials, Birmingham Clinical Trials Unit
- Michala Pettitt, Birmingham Centre for Observational and Prospective Studies
- Thomas Pinkney, Professor of Surgical Trials, Institute of Applied Health Research, University of Birmingham
- Matt Popplewell, Assistant Professor of Vascular Surgery, Institute of Applied Health Research, University of Birmingham
- Michael Wall, Consultant Vascular Surgeon, Black Country Vascular Network

### Audit Office Details

| | |
|---|---|
| Birmingham Centre for Observational and Prospective Studies (BiCOPS)<br>Birmingham Clinical Trials Unit<br>Public Health Building<br>University of Birmingham<br>Edgbaston<br>Birmingham<br>B15 2TT | BhamRED@contacts.bham.ac.uk |

### Project Lead Contact Details

| | |
|---|---|
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## 4. AUDIT SUMMARY

| | |
|---|---|
| **Full Audit Title** | Surgical Site Infections in Major Lower Limb Amputation – Transmetatarsal Extension: An International Multicentre Audit |
| **Short Title** | SIMBA-T |
| **Audit Design** | International multicentre, prospective audit |
| **Audit Duration** | Approx. 18 months |
| **Audit Objectives** | **Primary Objectives**<br>• Describe incidence of post-TMA SSI and wound breakdown<br>• Describe risk factors associated with these and clinical outcomes of post-TMA SSI.<br>**Secondary Objective**<br>• Describe centre specific pathways and policies surrounding TMAs |
| **Audit Outcomes** | • Describe centre specific pathways and policies surrounding TMAs<br>• Calculate a 30-day incidence of SSI post-TMA<br>• Calculate a 30-day incidence of wound breakdown post-TMA<br>• Identify the probable cause of wound breakdown post-TMA (e.g. ischaemia, haematoma or infection)<br>• Calculate a 30-day incidence of revision surgery post-TMA (to the same or higher level)<br>• Identify the patient and surgical risk factors associated with post-TMA SSI<br>• To calculate the incidence of complications related to SSI including, sepsis, acute kidney infection (AKI), |

| | |
|---|---|
| | mortality, in-hospital cause of death, increased length of stay or admission to critical care. |
| **Coordinating Centre** | Birmingham Centre for Observational and Prospective Studies |
| **Number of subjects** | >250 |
| **Eligibility Criteria** | Patients are eligible for inclusion in SIMBA-T should they meet the following criteria:<br>• Patients > 18 years of age<br>• Patients undergoing transmetatarsal forefoot amputation (including guillotine TMA ) with the intention of primary/delayed primary closure, partial closure (including leaving drain in situ) or healing by secondary intention.<br>• Emergency or elective TMA |
| **Duration of data collection** | Centres should collect data on eligible patients. Post-operative sequelae data points will be collected up until 30 days following surgery with follow up at 12 months. |

## 5. INTRODUCTION

In patients with chronic limb threatening ischaemia (CLTI) or diabetes related foot complications, transmetatarsal amputation (TMA) is often required to treat serious infection or remove gangrenous digits to promote a healing wound. This often follows an attempt at revascularisation of the limb. TMA preserves limb length as well as a functioning ankle joint, allowing patients to walk unaided with lower energy expenditure (compared to a major lower limb amputation (MLLA) with a prosthesis)[1-3].

Following amputation of the limb, surgical site infection (SSI) is common. We have recently reported the pooled incidence of SSI following MLLA which is estimated at 7.2%[4]. The Vascular Society of Great Britain and Ireland (VSGBI)[5] and National Institute for Health and Care Excellence (NICE)[6] have published guidelines with the aim of improving outcomes following MLLA surgery. Unfortunately, the incidence, predisposing factors and outcomes for SSIs in patients who have undergone TMA is less clear. SSIs following TMA may lead to revision to a more proximal MLLA, which is associated with prolonged hospital stay and increased morbidity and mortality and healthcare costs[1, 2, 7].

Although less common than MLLA, there were 1,872 TMAs performed in England in 2022-23[8]. Despite this, the reporting of outcomes following TMA are poor. Members of our study group recently performed a systematic review and determined that the pooled SSI rate following TMA was 24.0% using data from one randomised controlled trial (RCT) and four observational studies[9]. However, this was only based on 233 patients with heterogenous reporting methods and high risk of bias. Another systematic review, which focused on healing rates and outcomes following closed TMA reported a random effects pooled, post-operative infection rate as 16.7% (range 3.0% to 30.7%) and a random-effects pooled, dehiscence rate of 28.8%[10]. In the United Kingdom, the National Vascular Registry (NVR)[11] records the number of TMAs performed nationally but the outcomes of which are not routinely reported, due to low case ascertainment compared to Hospital Episode Statistics (HES) data. Although

revision rate to higher levels of amputation should be recorded by proxy, SSI is not a recorded outcome.

To address deficiencies in reporting and outcomes following MLLA, The Surgical Site Infections in Major Lower Limb Amputation (SIMBA) Audit[12] has recently been run, providing outcome data on approximately 1,000 patients who had MLLA. The results of this are yet to be published. Building on SIMBA, we aim to use same platform to deliver the Surgical Site Infections in Major Lower Limb Amputation – Transmetatarsal Extension (SIMBA-T) Audit, which will address the current lack of evidence , and understand the current management and outcomes in patients undergoing TMA.

## 6. PROJECT AIMS

i. Capture centre specific data regarding pathways and policies for patients undergoing TMA
ii. Calculate the 30-day incidence of SSI post-TMA
iii. Calculate the 30-day incidence of wound breakdown post-TMA
iv. Identify the probable cause of wound breakdown post-TMA (e.g. ischaemia, haematoma or infection)
v. Calculate the 30-day incidence of revision surgery post-TMA (to the same or higher level)
vi. Identify the patient and surgical risk factors associated with post-TMA SSI
vii. Calculate the incidence of complications related to SSI including sepsis, acute kidney infection (AKI), mortality, in-hospital cause of death, increased length of stay or admission to critical care.
viii. To capture 1-year outcome data for these patients (mortality, amputation revision, ambulation status) and assess the impact of SSI on these outcomes.

### 6.1 Primary Objectives

1) Describe incidence of post-TMA SSI and wound breakdown
2) Describe risk factors associated with these and clinical outcomes of post-TMA SSI, using the NCEPOD Lower Limb Amputation Report as a framework[13].

### 6.2 Secondary Objective

1) Describe centre specific pathways and policies surrounding TMAs

### 6.3 Outcomes

Outcomes are a modified version of the short-term core outcome set for MLLA, including problems with amputation healing and infection, mortality, requirement for re-admission, re-operation or further specialist treatment for complications[14].

Outcomes will include compliance with NICE guidelines on SSI prevention[6]. The Centres for Disease control and Prevention (CDC) definition will be used to identify SSI within 30-days of TMA[15]. However, if a bone/deep tissue sample taken intraoperatively during the TMA is positive on culture, this will be considered an incompletely debrided infection rather than a SSI. SSI will be limited to those apparent to the treating vascular clinicians within 30 days of surgery. It is recognised that this audit may not capture milder infections treated in the community; this will be accounted for in analysis and dissemination.

## 7. PROJECT DESIGN

### 7.1 Overview

SIMBA-T is an international, multicentre audit of practice disseminated via the Vascular and Endovascular Research Network (VERN: https://vascular-research.net). VERN is a trainee-led national research collaborative that is run by, and engages with, research-active vascular trainees and allied health professionals, and has expertise in running national and international audits of practice.

### 7.2 Setting

Hospitals providing emergency and/or elective TMA surgery in the UK and abroad recruited via VERN. TMA surgery can be performed within a vascular surgery department, orthopaedic department or other appropriate department. Based on current interest at least 50 units are

expected to be enrolled. Whilst the best practice policies are based on UK documents, SIMBA-T will also capture how non-UK centres practice aligns to these guidelines.

### 7.3 Target Population

Adults receiving emergency or elective TMA surgery.

### 7.4 Eligibility criteria

The audit will capture data on consecutive patients undergoing TMA. Any patients undergoing TMA due to complications of peripheral arterial disease (PAD), diabetes mellitus (DM), trauma, and other reasons are eligible for enrolment if they meet the specified criteria below. Eligible patients will be identified by screening data available to the clinical team; patients will not be approached/contacted during any part of SIMBA-T, and there should be no change to any patient care during the course of the audit. In patients undergoing TMA of both limbs during the duration of SIMBA-T data capture, so long as the patient is eligible, both sides will be included (as separate case records).

The following criteria should be used to identify patients are eligible to be enrolled for data capture:

- Patients > 18 years of age
- Patients undergoing transmetatarsal forefoot amputation (including guillotine TMA) with the intention of primary/delayed primary closure, partial closure (including leaving drain in situ) or healing by secondary intention.
- Emergency or elective TMA

### 7.5 Interventions

The study is observational and low risk. There are no interventions and only routinely collected data will be used. All patients will receive standard routine care, and what this entails will be collected as part of the audit.

### 7.6 Patient Pathway and Identification

Once a centre is open to SIMBA-T, data from consecutive patients undergoing TMA meeting the eligibility criteria will be collected prospectively. Data will be captured for each participant until 30 days following surgery (with a potential to extend to 1 year – see below).

Local Information Technology (IT) systems, theatre lists and in-patient lists will be used to screen for eligible patients.

In the event of a patient who previously had a TMA outside the SIMBA-T audit period (not entered into SIMBA-T) undergoes TMA revision, this patient is suitable for data capture and should be recorded as such in Research Electronic Data Capture (REDCap).

In the event of a patient already enrolled into SIMBA-T returning to theatre for revision of amputation (during the data capture period of SIMBA-T), this would be recorded as a "return to theatre" on the original data record and data entry for this record must be completed.

In the event of a patient already enrolled into SIMBA-T for an amputation on one limb has an amputation of the other (contralateral) limb, data regarding the second amputation should be entered into SIMBA-T as a new record.

## 8. DATA COLLECTION

### 8.1 Patient Entry

Key demographic data, baseline variables and intra-operative data should be collected as early as possible following TMA surgery, ideally at the completion of the operation.

Once eligibility is confirmed, the baseline Data Collection Tool (DCT) should be completed. When the data are uploaded onto the SIMBA-T REDCap database, a unique REDCap identifier will be allocated to the patient. This unique study number will be used in all correspondence between the SIMBA-T study office and the site. Linkage between the REDCap ID and patient should be maintained securely at hospital site.

Post-operative sequelae data points will be collected up until 30 days following surgery. In the case of SSI development, further details will be required regarding extent of infection and

subsequent patient outcomes. Data obtained using patient notes and electronic records; pre-operative assessment, clinic letters, theatre IT systems, discharge summary, and Accident & Emergency (A&E) and General Practice (GP) records (where available). No changes to normal follow up will be made and the patient will not be contacted to enquire about SSI unless this is standard in centre-specific care. SSI will be defined as per the 2024 CDC criteria[15].

### 8.2 Clinical Outcomes

*Data collected by clinical team at index admission, 30-day and 1 year follow up:*

1. Baseline patient demographics
2. Indication(s) for TMA
3. Intra-operative details of TMA procedure, including type of TMA performed
4. 30-day mortality incidence
5. 30-day SSI/wound breakdown incidence, and (if applicable) sequalae of this
6. 30-day complication rate
7. 1-year mortality, TMA revision and ambulation rates

### 8.3 Site level data

On enrolment to SIMBA-T, each centre will be asked to complete a baseline unit survey. This will collect data on individual centres clinical care pathways and policies surrounding TMA.

### 8.4 Recruitment Projection

With approximately 50 centres hoping to take part in SIMBA-T, it is anticipated that data on at least 250 patients may be captured over a 6-month period, based on data available from the SIMBA audit as well as other literature. We will, however, be happy to exceed this number in terms of both number of centres and number of patients.

| Table 1 – Key dates for SIMBA-T Audit | |
|---|---|
| First patient recruited | 1st Feb 2025 |
| Last patient recruited | 1st Aug 2025 |
| Last follow up data point (30-day outcomes) | 1st Sept 2025 |
| Last follow up data point collected (30-day outcomes) | 1st Oct 2025 |
| Last follow up data point (1-year outcomes) | 1st Aug 2026 |
| Last follow up data point collected (1-year outcomes) | 1st Sept 2026 |

Centres may open and close at any point within the time window for recruitment as prescribed above. It will obviously be the intention for centres to be open for the maximum time possible to maximise recruitment.

## 9. STATISTICAL CONSIDERATIONS

The statistical analysis of this audit will be undertaken by our statisticians based within the Institute of Applied Health Research at the University of Birmingham. The report of the audit will be prepared in accordance with the guidelines as set by the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement.

Continuous variables will be summarised with means and standard deviations; frequencies and percentages will be used for categorical variables. Univariate and multivariate analyses will be assessed by appropriate statistical techniques. Multilevel-logistic regression models will be used to allow for clustering at a centre or a country level**.** A p-value of $<0.05$ will be considered significant for all statistical methods used and the analysis will be completed using appropriate statistical software. The performance of individual hospitals will not be disclosed, and all subgroup analysis will include large patient cohorts to protect patient anonymity. No surgeon- or hospital-specific comparisons will be performed in the final dataset. Limb-based outcomes (for example, SSI) will be calculated per limb; patient-based outcomes (for example, morbidity and mortality) will be calculated by patient.

## 10. DATA HANDLING AND RECORD KEEPING

### 10.1 Data Management

Data will be collected at the following times:

- At the time of TMA
- At 30 days post operatively
- The REDCap database will be kept open to permit the follow up of patients one year after their TMA. This will be to assess the impact of SSIs on longer-term outcomes after TMA. Data on mortality, ambulation status, and need for revision surgery, will be collected. If this is feasible, one more team member can be added to the existing team to support the return of one-year data. It is expected that the overseeing consultant/attending will not change.

Data will be entered directly onto the SIMBA-T REDCap database by study collaborators at participating hospitals sites. REDCap[16, 17] is a secure, web-based software platform designed to support data capture of single and multi-site studies. It is encouraged that data will be uploaded directly to REDCap as close to the time of surgery as possible. Paper DCTs will be provided to centres to facilitate data capture when direct upload to REDCap is not possible at the time of surgery. No patient identifiable data will be transferred to REDCap.

The online SIMBA-T database is located at https://www.bistc.redcap.bham.ac.uk. SIMBA-T data management staff will check all incoming data DCTs for completeness, data consistency and compliance with the protocol. If discrepancies or missing data are identified, the SIMBA-T data management staff will raise queries with the research team at the participating hospital.

Data validation will be performed to confirm of case ascertainment and data accuracy. At the close of the data capture timeframe, centres will be asked to review theatre logs to ensure that all patients undergoing TMA during the data-collection timeframe were entered. Any patients not included will be added retrospectively; it is appreciated that not all data may be available retrospectively, but the SIMBA-T team will account for this during analysis and dissemination.

### 10.2 Data Validation

Data completeness will be quantified following the initial data collection. Any datapoints left blank will be considered incomplete. Data points recorded as “unknown” will count as complete data. Cases with <90% data completeness will be returned to the local centre for completion. If this is not possible, these cases will be excluded from the analysis, as is standard within international collaborative audits[18]. Individual patient records with less than 90% completeness of mandatory datapoints will be returned for completion; if this is not possible the patient will be excluded from the analysis. All centres will be required to validate data accuracy in 20% of their uploaded cases (randomly selected); 25% of datapoints (randomly selected) per case will be validated, equating to 5% of total datapoints captured. Any centre reporting accuracy of less than 90% will be required to validate a further 20% of their cases and the lead team member will be asked to investigate and report back to the SIMBA-T Management Group. Data validation will be undertaken independently by a team member not involved in the initial data collection.

### 10.3 Missing Data

The online database has been designed to allow sites to securely access an individual patient’s data for all DCTs throughout the study period. This means that any missing or erroneous data can be altered by the local investigators whilst the data collection period is ongoing. In order to maximise data completion and emphasise its importance to collaborators, participating centres with >10% missing data in mandatory fields (i.e. <90% data completeness) will be excluded from the study, as is standard within international collaborative audits[18].

### 10.4 Data Security and Data Protection

The security of the study database system is governed by the policies of the University of Birmingham. The SIMBA-T database will be hosted on the University’s REDCap system managed and maintained by the Birmingham Centre for Observational and Prospective Studies (BiCOPS).

Data management and data security within the BiCOPS will abide by the requirements of the General Data Protection Regulations (GDPR) and any subsequent amendments. The study will be conducted at collaborating sites in accordance with the current data protection requirements. Data will be acquired and stored on the REDCap platform. Access to data will be restricted, each individual collaborator entering data for SIMBA-T will have their own username and password. Each participant will be allocated a unique study number at entry. All communication will use this as the identifier. All data will be analysed and reported in summary format. No individual will be identifiable.

### 10.5 Confidentiality

Patient identifiable information will not be collected in this study. All participant data held at the University of Birmingham will be anonymised.

All data collected about participants will be identified using only a unique SIMBA-T study number (REDCap ID). This number will be automatically allocated via REDCap once a new patient record is created in the SIMBA-T database.

Any correspondence between the SIMBA-T study office and hospital sites will use the SIMBA-T study number only.

The linkage between REDCap study ID and participants will be maintained in strict confidence at participating sites. This data will not be submitted to the BiCOPS study office and will not be sent outside of the participating site. A template document will be sent to centres on enrolment to be overseen by the local lead, who will be responsible for ensuring this file is only stored on-site, is done so securely

Confidentiality of all participants' data will be maintained and there will be no disclosure of information by which participants may be identified to any third party other than those directly involved in the treatment of the participant. The participants will not by identifiable with regards to any future publications relating to this study.

## 11. ETHICAL APPROVAL

Every participating centre will register the audit locally prior to data collection (audit and service provision registration at all NHS sites involved). This audit does not require approval from the NHS Research Committee as per guidance by the healthcare Research Authority (see appendix 1). Centres outside of the United Kingdom should comply with local regulations.

The audit is required to be registered with each participating centre prospectively, prior to data collection. This is typically with the audit department, or 'Research and Development' department. Participating centres outside of the UK must comply with local regulations prior to commencement. The audit is open to all centres that undertake elective and/or emergency TMA. In the case of UK vascular units, often they comprise of a Hub and Spoke type model. A registered Hub site may be able to undertake data collection for the Spoke sites without registering the spoke site separately.

### 11.1 Audit Administration

The audit has been developed by a study management team with expertise in TMA surgery. The project will be under the auspices of the Project Leads (PL) and BiCOPS. The project will be overseen by a Study Management Group (SMG). This SMG will be chaired by the PL.

## 12. DISSEMINATION

### 12.1 Local Study Teams

Each centre will require the support of a named supervising consultant/attending (or equivalent), who will act as guarantor of all activity undertaken at that centre, and a data collection team.

Each participating centre will be responsible for identifying a site Lead and a data collection team. The site lead should be at least of a consultant level or equivalent. Where feasible the use of trainee collaboratives will be encouraged to aid in the delivery of this audit. The role of Site Lead is to:

- Promote the audit at site and facilitate delivery at site

- Liaise with the SMG
- Ensure that mechanisms for upload of data relating to eligible participants is in place
- Ensure appropriate local staff resources are maintained (cover provided for absence) to deliver the audit

The local audit team will be responsible for data collection and data validation. This team will comprise a maximum of a supervising consultant/attending and a further 4 individuals and can include medical trainees or allied healthcare professionals.

### 12.2 Publication Policy

The PL will co-ordinate dissemination of data from this audit. All publications using data from this audit to undertake original analyses will be submitted to the SMG for review before release. The success of the study depends on a large number of clinicians. For this reason, credit for the results will not be given to the committees or central organisers, but to all who have collaborated and participated in the study. Acknowledgement will include all local co-ordinators and collaborators, members of the study committees, the SMG and administrative staff. Authorship at the head of the primary results paper will be cited as a collaborative group to avoid giving undue prominence to any individual. All contributors to the study will be listed at the end of the report, with their contribution to the project identified. Those responsible for other publications reporting specific aspects of the audit may wish to utilise a different authorship model, such as “[name], [name] and [name] on behalf of the collaborative Group”. Decisions about authorship of additional papers will be discussed and agreed by the Project lead and the SMG.

To qualify for PubMed-citable collaborative co-authorship individuals must have either:

- Had a significant role in the set up and management of the study, including audit department registration, creation of a data collection team and engagement with VERN to ensure timely upload of data (with validation) and completion of the questionnaire

  **OR**

- Captured sufficient data to warrant authorship – this would be the equivalent of collecting baseline and follow up data on approximately 10 patients, although it is appreciated individuals may participate in only baseline data collection or only follow up data capture. This will be reviewed during the study period dependent on case ascertainment at each unit. Data collection is expected to be complete (>90% variables completed), and submitted in a timely manner

  **OR**

- (For consultants/attendings) provided oversight and support as detailed in the ‘‘Centre Eligibility and Team Roles” section.

The local lead at each centre will be responsible for ensuring that the SIMBA-T Management Group have the names and contact details of all collaborators who qualify for collaborative co-authorship at their centre. All collaborators will be given the opportunity to review draft paper(s) prior to submission. Whilst the SIMBA-T team appreciates the importance of this step, the team are also keen to ensure this stage does not add to significant delays in submission. All collaborators should inform the team of any changes in email addresses, and ensure their emails are checked regularly, as this stage will deliberately be kept short. Unless there are major issues or questions identified, collaborators will be given a single opportunity to comment on the paper before it’s returned to the writing group for further review within 72 hours. The writing group will make a final decision regarding the comments and edits made during this process.

Plain language summaries will be created and distributed to national amputation charities and key stakeholders.

### 12.3 Dissemination of Research Findings

The results of this audit will be submitted for publication in peer reviewed scientific journal, given the international nature of this audit it is anticipated that this will be reflected in the journal selected. Results of the audit will also be presented at meetings both national and international, according to the contributing nations. The findings of this audit may be used to inform the design of further studies into TMA SSI prevention.

### 12.4 Finance and Funding

This audit has been funded by the National Institute of Health and Care Research Health Technology Assessment (HTA) Application Acceleration Award (22/104). The project will be coordinated via BiCOPS and thus the burden of the cost will lie within the UK. Participating centres will not bear any costs for being part of this audit. Similarly, no financial reimbursement will be made to units or investigators for their involvement.

## 13. REFERENCES

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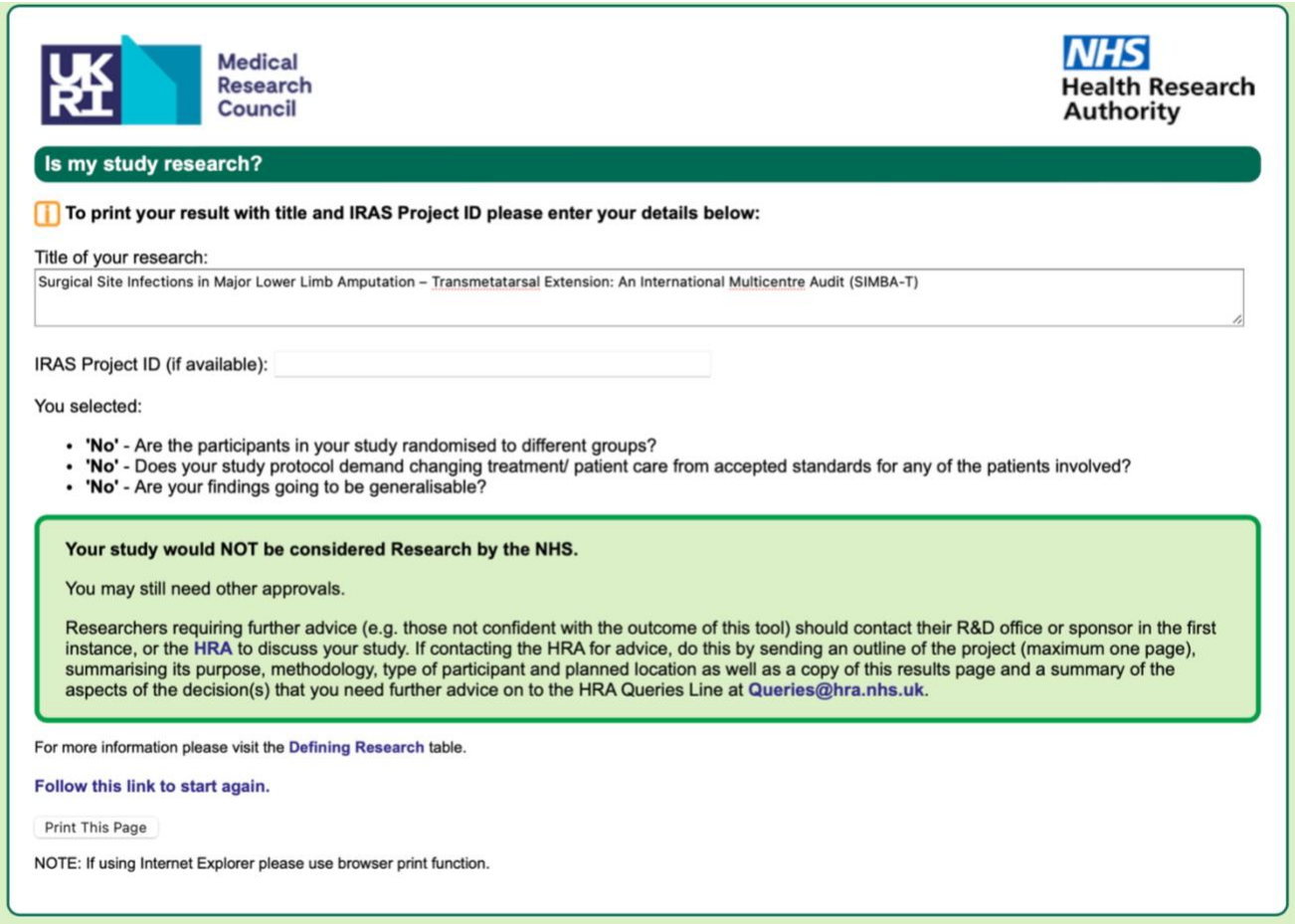
## APPENDIX 1 – HRA Decision Tool



Medical Research Council

NHS Health Research Authority

**Is my study research?**

**To print your result with title and IRAS Project ID please enter your details below:**

Title of your research:

Surgical Site Infections in Major Lower Limb Amputation – Transmetatarsal Extension: An International Multicentre Audit (SIMBA-T)

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

**Your study would NOT be considered Research by the NHS.**

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at Queries@hra.nhs.uk.

For more information please visit the Defining Research table.

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