Delegation Log

The principal investigator has responsibility for the conduct of the study at the participating organisation. The principal investigator can delegate tasks to other people at the participating organisation. Anyone who is delegated tasks by the principal investigator must fill in this log, and be confirmed by the principal investigator, before carrying out those tasks.

The principal investigator must confirm that people delegated tasks have been appropriately trained to carry out those tasks before they perform them.

The participating organisation must keep the original log up-to-date according to the requirements of the sponsor.

I confirm/ acknowledge that the information in this form is correct and that;

- I will remain responsible for the conduct of the study and reported data at this participating organisation.
- I will oversee the study at this participating organisation.
- I will authorise tasks to be delegated to people listed in this form.
- I will only delegate tasks to people who are appropriately skilled and trained to carry out those tasks.
- I will tell the people delegated tasks of their responsibilities in carrying out those tasks.
- I will make sure that no one who is to be delegated tasks will carry out those tasks before they have been delegated to them.
- I will make sure that no one who is to be delegated tasks will carry out those tasks before they have completed any training required to carry out the tasks.
- I will make sure that people delegated tasks receive the necessary information and training at the proper times.
- I will make sure that any and all changes to people delegated tasks, or the delegated tasks, are recorded on this form at the proper times.
- I acknowledge the Data Privacy Statement attached to this log.

Name of Principal Investigator	Principal Investigator's Signature	Principal Investigator's Initials	Start Date (dd/mmm/yyyy)	End Date (dd/mmm/yyyy)

STAFF SIGNATURE AND DELEGATION OF RESPONSIBILITIES LOG

Study Sponsor:	Newcastle-Upon-Tyne Hospital Foundation Trust	**IRAS Project ID:**	294528
Protocol / Study Number:	V2.0 July 2021	**Principal Investigator:**	Mr Sandip Nandhra
Protocol / Study Short Title:	FraiLTI (Frailty in chronic Limb Threatening Ischaemia)		
Participating Organisation No.:		**Participating Organisation:**	

Key of tasks

1. Coordinate approval communications/ submissions
2. Screen/ recruit study participants
3. Obtain informed consent
4. Confirm eligibility (inclusion/ exclusion)
5. Obtain medical/ medication history
6. Perform medical examination
7. Conduct study visit procedures (e.g. vital signs, height, weight, ECG)
8. Conducts specialist study visit procedures (e.g. photography, audio recordings)
9. Perform study related assessments
10. Make study related medical decisions
11. Evaluate study related test results
12. Collect biological samples/ material
13. Process, store or ship biological samples/ material
14. Randomise study participants (with or without IWRS/ IVRS)
15. Make (e)CRF entries or corrections
16. Sign off (e)CRFs
17. Resolve data queries
18. Maintain essential documents
19. Manage IMP/ device receipt, storage and temperature monitoring
20. Prepare and/ or dispense IMP/ device
21. Managed IMP/ device accountability
22. Assesses AE/ SAE severity and causality
23. Report SAEs
24. Receive/ access safety notifications
25. Activities related to regulatory communications/ submissions
26. Activities related to randomisation code break
27. Other*
28. Other*

29. Other* _____
30. Other* _____

31. Other* _____
32. Other* _____

(*) Other tasks that are specific to the study, or are local regulatory requirements, identified by the sponsor.

Use the key of tasks to complete the Study Task column. For each person listed in the Name column, record the number(s) of the task(s) delegated to that person. Numbers can be recorded consecutively, or as a range, e.g. 3, 4, 5, 6, or 3-6; 8-11. Tasks should only be delegated to people who are suitably qualified by education, training and/or experience to carry out that task/role.

If there are any additional study specific tasks not listed, add these to the “Other*” sections of the key.

This log should include all people who routinely see study participants, who carry out study protocol related tasks, or who are responsible for data collection/interpretation. Add new or replacement people as appropriate.

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Study Sponsor: Newcastle-Upon-Tyne Hospital Foundation Trust **IRAS Project ID:** 294528

Protocol / Study Number: V2.0 July 2021 **Principal Investigator:** Mr Sandip Nandhra

Protocol / Study Short Title: FraiLTI (Frailty in chronic Limb Threatening Ischaemia)

Participating Organisation No.: _____ **Participating Organisation:** _____

NAME (Please print)	**SIGNATURE** My signature below indicates: - I accept to carry out the delegated task(s) - I acknowledge the Data Privacy Statement attached to this document	**INITIALS**	**STUDY TASK** (Select from the key)	**START OF TASK(S)** (dd/mmm/yyyy)	**PI SIGNATURE**	**END OF TASK(S)** (dd/mmm/yyyy)	**PI SIGNATURE**

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Comments: Please initial the box if there are no comments ☐

(To be completed by the Principal Investigator at the end of the study).

I confirm that the information in this form is accurate and complete.

Name of Principal Investigator *(please print)*	**Signature**	**Date *(dd/mmm/yyyy)***

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Data Privacy Statement

The above named Study Sponsor, being a public institution concerned with sponsoring health care research for the public good, will process the Personal Data that you provide in this staff signature and delegation log (together with associated personal data that you may provide as deemed necessary by the Study Sponsor, including CVs, training certificates and so forth, as well as other data about you obtainable from public sources or present in Source Data relating to the conduct of this Study) as necessary to fulfil its purposes in relation to this study and future studies for use by public institution sponsors on the basis of the public interest in so doing (i.e. the legal basis for the processing of your personal data by and on behalf of the Study Sponsor as data Controller is that it is a task in the public interest. Your Personal Data processed for the purpose of this Study (or for future studies, as below) will not include Sensitive Personal Data, as defined in the Data Protection Legislation.

The overarching purpose of the Study Sponsor in processing your Personal Data in relation to this study is the exercise of its oversight responsibilities as Sponsor, as defined in The UK Policy Framework for Health and Social Care (and in clinical trial and/or clinical investigation legislation, as and where applicable). Copies of the documents containing your Personal Data may be taken by agents of the Study Sponsor to be provided to the Study Sponsor and / or sent to the Study Sponsor by the participating organisation, as required by the Study Sponsor and as appropriate for the maintenance of its oversight of study activities, including oversight of the appropriateness of persons delegated to undertake such activities. In addition, the Study Sponsor may process your Personal Data for the purposes of determining the feasibility of future research (i.e. in considering the suitability of the above named Participating Organisation for participation in future research studies).

The Study Sponsor will only process your Personal Data as required to fulfil its purposes in relation to this study and future studies (as described above), including processing only that data which is necessary for its purpose/s and retaining your personal data only for as long as required for its purposes (including, but not limited to, adhering to any legal or best practice requirements on the duration of retention of source data and other data relating to the conduct of health care research). Your Personal Data will be securely transferred to the Study Sponsor, and held there, in accordance with the data security policies of the Study Sponsor, access to, or copies of which, will be provided upon request.

In undertaking its obligations as a Sponsor of research, the Study Sponsor may make available your Personal Data to regulatory bodies or other parties with a legal duty, public duty or other legitimate interest in the oversight of healthcare research and the licensing, commissioning, etc. of healthcare interventions.

You have the following rights regarding your personal data:

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- To be informed – you can ask the Study Sponsor what Personal Data they are processing about you and why.
- To access – you can ask the Study Sponsor to see the Personal Data that they hold about you and obtain a copy.
- Rectification – you can ask the Study Sponsor to correct any inaccurate information that they hold about you.
- Restriction – you can ask the Study Sponsor not to process information about you if the information is inaccurate, processed unlawfully, or no longer needed for the stated purpose.
- To object – you can ask that the Study Sponsor ceases its processing of your Personal Data, which it must do unless it is able to demonstrate compelling legitimate grounds for the processing which overrides your interests, rights and freedoms or that its processing is necessary for the establishment, exercise or defence of legal claims

Please note that if in exercising these rights you compromise the ability of the Study Sponsor to fulfil its stated purposes, you may be removed from your role in this study.

If you want to ask about your rights, or have any other questions or complaints about how the Study Sponsor has handled your Personal Data, you can contact the Study Sponsor at any time via Samantha Jones, cardiovascular research, Freeman hospital. Telephon**e:** 0191 244 8457. Should you wish to contact the Data Protection Officer of the Study Sponsor you may do so via The Newcastle upon Tyne Hospitals NHS Foundation Trust Newcastle Joint Research Office, Regent Point Newcastle NE3 3HD

If you are not satisfied with the response you receive to any questions in relation to your Personal Data or any requests that you make in order to exercise your rights in relation to your Personal Data, or if you believe that your Personal Data is being processed in a way that is not lawful, you can complain to the Information Commissioner's Office (ICO).