**Instructions**

**Please delete this page prior to submission.**

Once the protocol is complete, please send a copy to darfi@liverpoolft.nhs.uk two weeks prior to the next DARFI committee meeting which can be found at: <https://www.darfi.net/propose-a-study/>

Please complete all the sections within the protocol below and **DO NOT** delete or amend any of the headings.

Please amend the footer with your protocol version and date.

Text in **green** is a prompt for the sort of information we would like you to include.

**A DARFI Study**

**Into**

**X**

**Study lead:** **Lead PI Name**

**Protocol Version:** 1.0.0

**Protocol Date: xx/xx/20xx**

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# Background

## Study Management Group

**Personnel involved in the management of the proposed study.**

Mr Thomas Rogers

**The PI Name** will ensure that LUHFT’s local research governance committee is regularly updated with the study’s progress.

Final approval for new study sites to commence data collection and upload will be authorised by LUHFT’s R&I once all site has issued confirmation of capacity and capability.

## Scientific Advisory Group

**Clinicians and scientists involved in advising creation of the proposed study.**

## Partner Sites

Partner sites and associated local PIs to be listed following expression of interest for involvement in study which can be initiated here: <https://bit.ly/DARFI-EoI>

## Study Delivery Timeline

**Please outline a timeline for advertising the study, data collection window, analysis period and dissemination timeline.**

## Executive Summary

**Please outline a summary of the most important information for your proposed study.**

## About DARFI

The Database of Atypical and Rare Fractures and Injuries (DARFI) is a collaborative platform for the study of atypical and rare fractures and injuries on a national scale to better understand their epidemiology and improve their outcomes.

# Introduction

**Introduce your study and outline why it is needed.**

## Study Aims

**What are the primary and secondary aims of your study?**

# Methods

Data will be collected retrospectively by enrolled centres using their hospital’s electronic notes system. Patients treated between **start date** and **end date** (minimum **xx** month follow up) will be included. We aim for a study population of over 50 patients.

Patient details will be pseudonymised and centres will keep a list of which the pseudonymised number correlates to which patient locally. This list will be kept in a secure file locally by each site’s PI.

## Study Design

## Setting

## Project Timeline

## Patient Eligibility

**Inclusion criteria**

**Which patients are you including? Between which date ranges? What follow up criteria must they have?**

**Exclusion criteria**

Patients that are excluded via the National Data opt-out scheme

Less than **xx** month follow up

Incomplete data

Children <16

## Patient Identification

**How will you identify these patients? Which data sources will you want partner sites to look through?**

Patient identifiable data will be anonymised to a number on the centralised system and the list of these numbers and the patients they refer to will be kept locally.

## Data Points

**What are your end data points that you will be looking to collect?**

## Follow Up

**What is the minimum follow up for each patient you would expect in order for them to be included?**

## End of Study

**Define what will be the end of study point. Usually, this is the last date of the data collection window.**

## Data Collection and Storage

Data will be collected using either an encrypted, password protected Excel spreadsheet or directly using a dedicated REDCap form. The data will be stored on REDCap in line with DARFI’s SOP. The data will be held by Liverpool University Hospitals Foundation Trust (LUHFT) which will act as the data controller.

The following data will be collected and stored on a central, electronic database with multiple choice options:

**List your data collection variables here such as:**

**Age**

**Sex**

**Date of injury**

**etc..**

## Statistical Analysis Plan

The study will use convenience sampling since the national incidence of this injury remains unclear.

**How do you intend to analyse the data? What tests will you be planning to perform? What software will you be using? Will you be seeking support from somebody else? Please be as descriptive as possible for what steps you intend to take.**

## Local Governance and Ethical Approval

Agreements are in place between Liverpool University Hospitals NHS Foundation Trust Research & Innovation Department and participating organisations, covering all associated DARFI studies.

Ethical approval for DARFI was obtained on 1st February 2024 from the NHS HRA South West - Central Bristol Research Ethics Committee (REC reference: 24/SW/0015, IRAS ID: 331288), covering all associated DARFI approved sub-studies. Permission is given via REC approval to collect this data retrospectively without individual patient consent.

Indemnity for this study is via the NHSLA.

## Quality Assurance

**Design:** Meetings to consider previous literature and study design. **Any other steps taken to ensure Quality Assurance of the design stage?**

**Data completeness:** **How will you ensure that the data collected and uploaded is complete and accurate?**

**Validation: How will you ensure that the data collected and uploaded is valid?**

Central monitoring will be conducted to ensure the validity of the uploaded datasets.

## Authorship and Mini-teams

## Patient and Public Involvement

**Specific PPI involvement in the creation of the study?**

Patient and public involvement was undertaken throughout all stages of the design, development, and delivery of DARFI.

# Expected Outputs

**What sort of output are you expecting from this study i.e. poster/podium presentation, publication?**

# Acknowledgements

We thank the **Liverpool University Hospitals NHS Foundation Trust Research & Innovation Department** for kindly hosting DARFI on their REDCap servers.

**Website:** <https://www.liverpoolft.nhs.uk/about-us/research>

# References

**Please list any relevant references which have been mentioned in the study protocol.**