FLARE Trial Site Manual

A randomised trial to determine the clinical and cost effectiveness of repairing flexor digitorum profundus (FDP) alone versus repair of both FDP and flexor digitorum superficialis (FDS) for treatment of complete zone 2 flexor tendon injuries: the FLexor repAir and REhabilitation (FLARE) Trial

Short title: FLexor repAir and REhabilitation (FLARE) Trial

ISRCTN number: 10918157

IRAS number: 316277

REC reference: 23/NW/0004

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Contents

1. Introduction and contact details

Welcome to the FLARE team!

We would like to express our thanks for your interest and your participation in the delivery of the FLARE trial.

This is the FLARE Trial Site Manual. It contains information about the details of the trial and provides instructions and advice about the day-to-day management of the trial; including how to conduct trial activities, trial visits, report adverse events, and process a participant's change of status. Use of this manual is essential to ensure that all procedures and activities described in the protocol are adhered to and performed consistently at each participating centre for the duration of the trial.

The York Trials Unit (YTU) team will be your point of contact for the trial throughout the initial set up phase, during patient recruitment, and follow up. If you have any questions or concerns, please contact us at any time via ytu-flare-trial@york.ac.uk.

FLARE WhatsApp group

The WhatsApp group is designed to keep the FLARE trial community updated, share tips and successes. These group rules must be followed:

- Please use this to discuss FLARE trial recruitment/retention in general terms and in a supportive manner.
- No patient identifiable information should be transmitted to this group.
- You are responsible for the content of any messages you send. NHS information governance guidance should be adhered to.

To join the FLARE trial WhatsApp group, email ytu-flare-trial@york.ac.uk with your name, hospital name and mobile number, or scan the QR code below.

FLARE Trial on X and LinkedIn

The X and LinkedIn feed will be used to communicate trial updates and achievements.

Follow us on X: @FLARE_ _Trial

Follow us on LinkedIn: FLexor repAir and REhabilitation (FLARE) Trial

It is important that **no patient identifiable information** should be transmitted on X or LinkedIn.

FLARE Trial website

The FLARE trial website (www.flaretrial.com) was designed to inform site teams about the FLARE trial.

On this website, you can find out which sites are participating in the FLARE trial across the UK, useful resources for researchers, FLARE study specific training modules, trial documentation (e.g. current protocol and patient information sheet), and a FAQ section. If you have any specific questions, please query these with the YTU team via email: ytu-flare-trial@york.ac.uk

Contacts details

If you have any questions or concerns, please contact us at any time.

Table 1: Key contact details

Key contact	Role	Organisation	Contact details
FLARE team			ytu-flare-trial@york.ac.uk
Matthew Gardiner	Co-Chief Investigator	Frimley Health NHS Foundation Trust	matthew.gardiner@nhs.net 07870 619627
Emma Reay	Co-Chief Investigator	South Tees NHS Foundation Trust	emma.reay1@nhs.net
Liz Cook	Trial Manager	York Trials Unit	liz.cook@york.ac.uk 01904 321522
Michelle Watson	Trial Coordinator	York Trials Unit	michelle.watson@york.ac.uk 01904 321102
Emma Moatt	Trial Coordinator	York Trials Unit	emma.moatt@york.ac.uk 01904 325764

Postal address for trial correspondence:

FAO: FLARE Trial, York Trials Unit, Lower Ground Floor, ARRC Building, Department of Health Sciences, University of York, York, YO10 5DD

2. Study Specific Training and Delegation of Tasks

All of the following steps relating to the Study Specific Training (SST) and completion of the delegation log and data privacy statement need to be completed in order to gain access to the main FLARE REDCap database.

Study Specific Training (SST)

Team members must be appropriately trained before undertaking any delegated tasks on the trial. Hence there are three SST modules to complete, depending upon your role and responsibilities in the trial:

1. Trial Overview
2. Consent
3. Finger Range of Motion and Grip Strength Data Collection

Table 2 provides a guide of which SST modules each team member could complete. However, it is for the Principal Investigator (PI) and site team to determine which modules to complete based upon their completed delegation log of duties. **Everyone is required to complete the Trial Overview training module.**

To complete your training please:

1. Go to www.flaretrial.com, scroll over to the 'For Site Staff' heading and then click on 'Study Specific Training' to view the Study Specific Training (SST) modules.
   If you cannot view the SST modules online, please refer to the FLARE eISF for the Powerpoint versions of the FLARE SST modules.
2. Complete the SST modules required.
3. Upon completion of the SST modules, request your SST certificate and record your FLARE training by clicking 'Complete your FLARE Trial Training Record Form' at the bottom of the SST webpage on the FLARE website (www.flaretrial.com). This will open a Google Form for you to complete.
   If you cannot access the Google Form, please email YTU and we will send a Word version of the form to complete.
4. YTU will email your SST certificate to the NHS email address documented within the FLARE Trial Training Record Form.
5. File your SST certificate into the FLARE eISF.

Please note that we would recommend that you familarise yourself with key trial documentation, such as the trial protocol, FLARE Trial Site Manual, SIV slides, Patient Information Sheet, and the informed consent form. The current SIV slides are available via the following link: https://www.flaretrial.com/trial-documentation.

Training log

A training log will not be supplied to sites for completion. In order to streamline tasks where possible, an automated system has been developed so that once site team members have completed their SST modules and the FLARE Trial Training Record Form, the trainee's details are recorded in an automated FLARE master training log. A copy of the completed site training log can be requested by the site via email to the YTU team.

GCP and research CV requirements

Only the site PI needs to provide a Good Clinical Practice (GCP) certificate and research CV, which should be filed in the eISF.

To access the NIHR Good Clinical Practice eLearning module, go to https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm or please click here.

To access the NIHR Research CV template, go to https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv/ or please click here. Please ensure that you have signed and dated the CV.

Delegation of tasks

The FLARE delegation log needs to be completed by everyone who is being delegated to complete FLARE trial tasks through their own REDCap account. The PI is responsible for ensuring that all staff at their site are appropriately trained for the tasks that they have been delegated.

Completion of the delegation log and data privacy statement

Flowchart 1 below displays the delegation log and data privacy statement completion process.

Flowchart 1: Delegation log and data privacy statement completion process

Email ytu-flare-trial@york.ac.uk requesting access to the FLARE trial delegation log on REDCap and state your full name, NHS email address and hospital name. If you have previously worked on a YTU trial that required REDCap access, please include your YTU REDCap username. This step is not required if you have already submitted a FLARE Trial Training Record Form.

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Discuss tasks you will be delegated to complete with the PI.

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The YTU team will process your REDCap access; please check your inbox/spam/junk folders for an email notification from REDCap regarding your access. Please do not use another person's REDCap account for delegation log and data privacy statement completion whilst you are waiting for your REDCap account to be set up. **The delegation log and data privacy statement must be completed via your own REDCap account.**

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Once you have access to the FLARE delegation log on REDCap, log into your REDCap account and click 'FLARE Site Set Up' under 'My Projects'. Please note, your username is your NHS email address.

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Click on 'Record Status Dashboard'.

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Scroll down the webpage to find your name under the 'Record ID' column, and then click on the dot within the 'Delegation Log- Data Privacy Statement'.

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Read the Data Privacy Statement and respond to the statement 'I acknowledge I have reviewed the data privacy statement and agree to its stipulations'. Change the 'Form Status' to 'Complete' and click 'Save & Exit Form'.

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Click on the dot next to 'FLARE Site Delegation Log', enter your initials, trial role, select the delegated duties you will be undertaking, enter your start date and then sign and date the delegate section. Keep the 'Form Status' as 'Incomplete' and click 'Save & Exit Form'. The end date should remain blank. Some of the delegated duties can only be completed by specific site members. Please refer to Table 2 for further information.

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Notify the PI that your delegation log entry is ready for review and sign off.

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PI logs into their own REDCap account, reviews the delegation log entry and then signs and dates the PI section. Change the 'Form Status' to 'Complete' and click 'Save & Exit Form'.

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Notify the YTU team that your data privacy statement and delegation log entry have been fully completed and signed off. In your email to the YTU team, confirm whether you will be a blinded or unblinded team member.

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The YTU team will review your delegation log entry against your FLARE Trial Training Record Form. If there are no queries, and your site is open to recruitment, access to the main FLARE REDCap database will be granted.

Delegation Log- Principal Investigators only

If you are the Principal Investigator, please complete the steps specified above using your own REDCap account, in addition to completing the *Delegation Log- PI Responsibilities instrument*. **The *Delegation Log- PI Responsibilities instrument* does not need to be completed for site team members, nor Associate Principal Investigators (API).**
Within your delegation log entry, please ensure you select all of the delegated duties.

Delegation log key points

- **Please do not complete an end date** on your delegation log entry. This will be completed in the future if you stop working on the study.
- **If you are struggling to access REDCap,** please email the YTU team (ytu-flare-trial@york.ac.uk).
- **Please do not complete the trial close out section** of the delegation log until the trial has finished.
- **Please use your own REDCap account to complete the FLARE delegation log and data privacy statement.** Do not complete the delegation log and data privacy statement through another user's REDCap account.
- **Please note when ticking delegated duty 'H. Randomise trial participants' that blinded and unblinded access to the main FLARE REDCap database cannot be granted on a per patient basis.**
- **The only individuals who are exempt from completing the FLARE Study Specific Training and the delegation log are:**
  1) surgeons who are completing the surgical procedure itself only (not confirming eligibility nor completing randomisation, for example). However please ensure that there is a trained and delegated surgeon able to confirm eligibility, either in person or remotely, and a delegated unblinded team member to complete randomisation and REDCap data collection.
  2) hand therapists who are completing the finger range of motion and grip strength data collection only and not REDCap data entry, nor any other trial-related tasks. However, we recommend that the hand therapists familiarise themselves with the finger range of motion and grip strength data collection instructions available within the FLARE Trial Site Manual, section 16: Hand Rehabilitation, Finger Range of Motion and Grip Strength.

Delegation log- Next steps required when a change needs to be made

Q: What do I do if the PI and I (delegate) have signed off the delegation log entry and then a delegated duty is added?
A: The PI is required to log into their REDCap account and re-sign the 'PI signature' on the delegate's delegation log entry, along with updating the date of PI signature.

Q: The PI and I (delegate) have signed off the delegation log entry and now a delegated duty needs to be removed. What do I need to do next?
A: Delegate to remove the delegated duty. No signatures required.

Q: What do I do when a delegated member leaves the site team?
A: The 'end date' should be entered onto their delegation log entry in REDCap, and the YTU team need to be notified. The PI is not required to complete the trial close-out section of the delegation log entry at this timepoint.

Q: I have added an end date to my delegation log entry in error, what do I do?
A: Anyone can delete the end date.

Q: I completed my delegation log entry through another user's REDCap account, what do I do now?
A: Delegate needs to re-sign their delegation log entry using their own REDCap account, and update the date of delegate signature.
If the principal investigator has signed off a delegation log entry via another user's account, they need to log into their own REDCap account, re-sign the delegation log entry and update the date of signature.

Table 2: Delegated tasks, who they can be completed by, and SST modules to complete

Delegated task	**Suggested team members who can complete this task***	**Suggested Study Specific Training modules to complete**
A. Screening potential study participants	Surgical, research and hand therapy team	Trial Overview
B. Confirmation of trial eligibility	Surgeons only	Trial Overview
C. Obtain informed consent (explain study risks and objectives)	Surgical, research and hand therapy team	- Trial Overview - Consent
D. Clinical evaluations (including Range of Motion)	Research team, hand therapists and surgical team	- Trial Overview - Finger Range of Motion and Grip Strength Data Collection
E. Source document entry (i.e. Medical notes)	Surgical team, research team and hand therapists	Trial Overview
F. CRF completion/data entry (paper and electronic)	Surgical team, research team and hand therapists	Trial Overview
G. Perform flexor tendon surgery	Surgeons only	Trial Overview
H. Randomise trial participants	Unblinded surgical team and research team	Trial Overview
I. Correction of CRFs/resolving data queries	Surgical team, research team and hand therapists	Trial Overview
J. Sign off CRFs	Site PI *(end of trial)*	Trial Overview
K. Reporting adverse events, SAEs and SUSARs	Surgical team, research team and hand therapists	Trial Overview
L. Review and assessment of adverse events & SAEs	Surgeons only	Trial Overview
M. Maintaining ISF and study documents	All team members	Trial Overview
N. Complete unblinding if required	Unblinded team members	Trial Overview
Other duties specific to above study, please specify below	To be decided by site PI	Consider the following modules; - Trial Overview - Consent - Finger Range of Motion and Grip Strength Data Collection

* Please note that blinded members of the surgical team can complete follow-up activities, provided they have had no involvement with the participant's randomisation and surgery.

Surgeons listed on the study delegation log for other duties (e.g., confirmation of trial eligibility, randomise trial participants) should also be delegated 'G. Perform flexor tendon surgery'.

Delegation log entry download

If you wish to download a PDF copy of the completed delegation log entries, please refer to subheading 'Printing REDCap instruments with saved data as a PDF' within section 22 of this Manual.

3. REDCap database

The FLARE Trial uses REDCap for data collection. REDCap can be accessed by going to https://redcap.york.ac.uk/

Instructions regarding using REDCap are available in section 22 (REDCap database), or please follow the hyperlinks below;

Logging onto REDCap

Creating a patient record on REDCap

Searching for a participant record

Viewing 'Records' on REDCap

Completing instruments on REDCap

Missing fields

Saving instruments with incomplete data

Making changes

Repeatable instruments

Printing REDCap instruments for completion on paper

Printing REDCap instruments with saved data as a PDF

How to randomise on REDCap

4. Screening and eligibility

Screening Population

All patients who are 16 years old and over with lacerations in the palm or finger consistent with a zone 2 flexor tendon injury should be screened for the study.

In practice this includes patients with a volar laceration, anywhere along the finger from DIPJ crease to distal palmar crease, associated with reduced/painful active range of movement of their DIPJ and PIPJs. This can include multiple digits, please see Table 3 below for further clarification.

Essential: All patients screened **(eligible and ineligible)** must be logged in REDCap using the 'Add new record' function, and the *Screening and Eligibility instrument* completed.
Optional: A Screening and Enrolment Log will also be provided in Excel format, located in your eISF. It is optional to complete this and is available to assist local site screening procedures, if required. If used, all screening data must also be logged in REDCap. This Screening and Enrolment Log will not be monitored by the YTU team.
Screening summary information: Should you wish to obtain a summary of your site's screening data for local reporting processes, please contact the YTU team by email.

Assigning a participant ID number

A unique 7-digit participant ID number must be entered on the *Screening and Eligibility instrument*. Your site will be provided with a list of unique participant ID numbers to use, please allocate numbers sequentially from the list provided. If it is helpful, you may record that a number has been allocated on the list so it is clear which number should be used next.

- The first 3 digits represent the site ID number and will be the same for all patients at your site.
- If a duplicated participant ID number is entered, an error message will appear.
- **Please ensure the first 3 digits of the participant ID are entered correctly to enable REDCap to successfully randomise the patient, if needed.**
- **If the participant ID is entered incorrectly, do not amend, please notify YTU.**

Eligibility criteria at screening

Further clarification to assist with application of the inclusion/exclusion criteria is given in Table 3. If there are any questions, please contact the YTU team or the FLARE Trial WhatsApp group. If medical oversight is required, the query will be directed to the Co-Chief Investigators (Co-CIs) or a clinical co-applicant. **Please ensure that no patient identifiable information is included in the query.**

Table 3: Eligibility criteria at screening

The answer to ALL inclusion criteria must be YES for the patient to be eligible	
Inclusion Criteria	***Clarification***
Patients aged ≥ 16 years old	The number of flexor tendon injuries are small and the rehabilitation potential in those under 16 is different from adults. Those under 16 would therefore not be representative of the population as a whole.

The answer to ALL exclusion criteria must be NO for the patient to be eligible	
Exclusion Criteria	***Clarification***
Injuries affecting more than one digit or the thumb	Please base your decision, and complete question 13 of the *Screening and Eligibility instrument*, upon the following: Injuries that would be eligible for participation: · One digit injured only with both FDS/FDP tendons severed. · Multiple digits injured - only one digit with both FDS/FDP tendons severed, any other injured digits have superficial injury. · Multiple digits injured – only one digit with both FDS/FDP tendons severed, other injured digits may have a partial tendon injury. Injuries that would be ineligible for participation: · Multiple digits injured – multiple digits with both FDS/FDP tendons severed. The thumb is excluded as it only has a single flexor tendon.
Injuries outside of Zone 2	The anatomy of the flexor sheath within zone 2 is unique and the outcome of injuries within that zone are known to have more variable outcomes than the other flexor tendon zones of the hand, therefore no direct comparison can be made between zone 2 and the other flexor tendon zones. **It is important here to screen all patients with a laceration from tip to palm.** A zone 2 injury would be if the repair of the tendon is within zone 2 – A1 pulley to FDS insertion. It is not the location of the skin cut or sheath cut. For instance, a laceration could be in the distal palm just proximal to the A1 pulley but if the digit is flexed at the time the injury (and repair) will be within zone 2. It is likely that the zone is determined by the position of the distal end whilst doing the repair. Both tendons need to be in zone 2. The *Primary Surgery instrument* on REDCap captures the sub zones.
Injuries affecting multiple zones	The outcome from repair of a flexor tendon which has injuries in more than one place along its length cannot be compared to a single injury, as each insult to the tendon has an effect on eventual outcome.
Clinically infected wounds	Infected wounds behave differently than clean non-infected tissue and the presence of the infection would confound the outcome from the flexor tendon surgery.
Closed flexor tendon injury	Closed flexor tendon injury of the zone 2 flexor tendons is extremely rare and the surgical intervention to explore and repair this type of injury is not directly comparable to open injuries.
Previous tendon, bone or joint injury in the affected digit	Any pre-existing deformity of the digit which could have an effect on the rehabilitation potential of that digit requires exclusion. Any previous tendon, bone or joint injury could

	reduce the function and range of movement of that digit confounding the results of the flexor tendon surgery.
Patient does not have capacity to give informed consent	If a patient does not have capacity to give informed consent for surgery, then they will be unable to give informed consent to be involved in the study.
Patient unable to complete follow up requirements	Gathering outcome measures is key to the successful assessment of our study interventions, therefore any patient not able to complete the follow up requirements should be excluded.
Contraindication to surgery	If a patient is not fit for surgical intervention they will not be able to undergo either of the study interventions and therefore should be excluded.

Ineligible patients

Add a statement into the patient's medical notes documenting when the patient's eligibility was assessed, by whom, confirmation that the patient was ineligible, and their participant ID number. Do not approach the patient for consent. Treat as per standard care. Please ensure the *Screening and Eligibility instrument* is completed on REDCap.

Reasons for not approaching the patient

Please record any reasons for not approaching an eligible patient on the *Screening and Eligibility instrument* in REDCap. Some examples of these reasons include but are not limited to; patient being in police custody or a prisoner, and patient left the department.

Eligible patients

Please continue onto section 5 (Informed consent) for further information.

FLARE participant checklist

A FLARE Trial participant checklist is available within your eISF and describes all tasks to be completed by the site team and the associated instruments that require completion on REDCap. Use of the checklist is optional and will not be monitored by YTU.

Eligibility criteria at screening frequently asked questions

Q: Does the exclusion criteria 'Previous tendon, bone or joint injury in the affected digit' also refer to the current injury?
A: No, this criterion does not refer to the current injury.

Q: If, from a clinical point of view, you are sure it is a partial injury, can you exclude the patient at this [initial screening eligibility assessment] point?
A: All patients who are 16 years old and over with lacerations in the palm or finger consistent with a zone 2 flexor tendon injury should be screened. You are unlikely to be able to confirm whether there is complete division of FDP and FDS in zone 2 of a single finger at the initial eligibility assessment. There are two stages to the eligibility assessment; complete division of FDP and FDS will be confirmed during the intraoperative eligibility assessment. If, during surgery, you see that there is not complete division of FDP and FDS, then the patient should be excluded.

Q: For the *Screening and Eligibility instrument*, who should be named for question 23 'Name of delegated surgeon confirming eligibility'?

A: The person named here should be the delegated surgeon who confirmed whether the patient was eligible or ineligible.

Q: If the patient has an underlying fracture, are they still eligible for participation?
A: No, as it impacts on their rehabilitation regimen.

Q: If the patient requires a foreign body removal, are they still eligible for participation?
A: Yes.

Q: Are bilateral injuries included in the trial?
A: No- bilateral injuries which involve complete severence of flexor tendons should be excluded.

5. Informed consent

Patient's who meet the FLARE Trial eligibility criteria need to be fully informed about the trial in order to decide about their participation. There is no minimum amount of time specified for patients to consider participation, but we do encourage that the patient is given as long as possible, where time allows. Patients are welcome to discuss the trial with family and friends. The following materials are available to support consent discussions;

- Summary Patient Information Sheet (PIS)
- Patient Information Sheet (Full)
- Patient Information Sheet (Animation)
- Patient Information Sheet (Audio Recording)
- Patient Information Sheet (Infographic)

The site team need to assure themselves that the patient is fully informed before completing consent. If patients lack capacity to consent, they are not eligible to participate in FLARE.

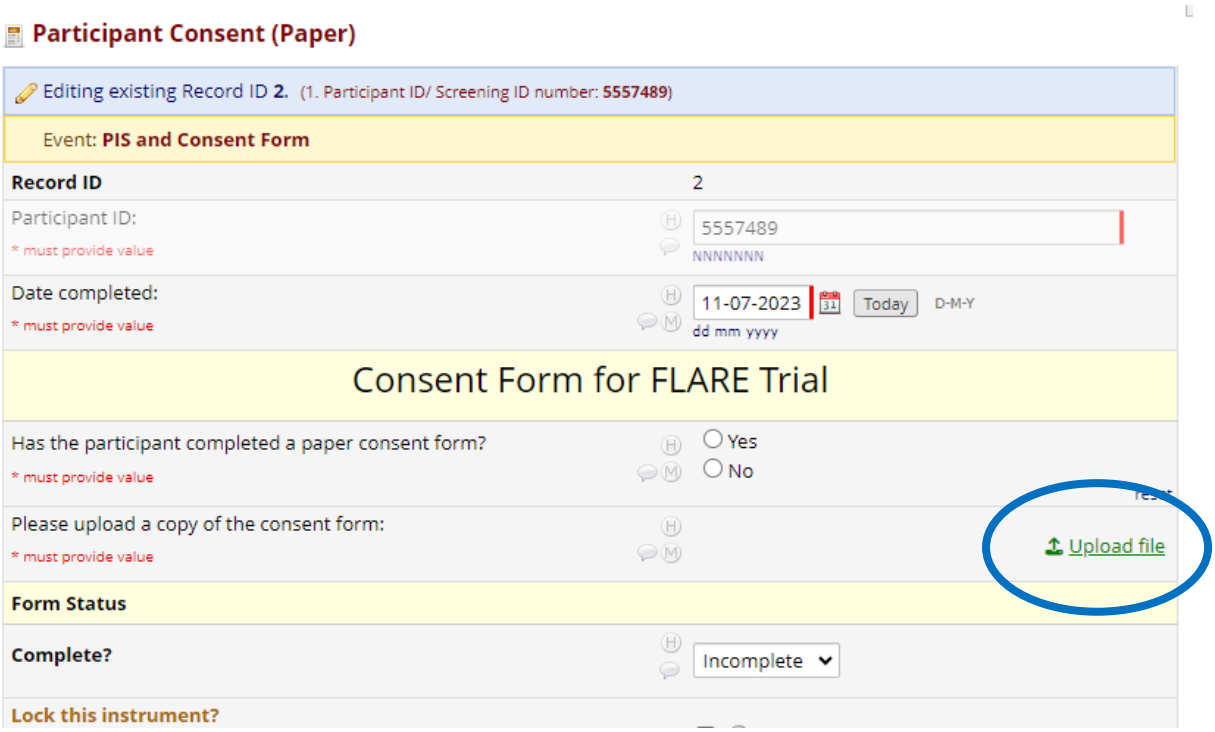
<u>Obtaining informed consent electronically with the patient in person</u>

- Ensure the patient has had the opportunity to read the PIS and ask any questions they may have
- Find the participant's REDCap record; guidance on how to complete this can be found in section 22 (REDCap database)
- Once you are on the participant's Record Home Page, select the dot on the 'Patient Information Sheet & Participant Consent Form' row
- Complete the form with the patient and a witness (if required)
- Change the Form Status to 'Complete', and click 'Save and Exit Form'

<u>Obtaining informed consent on paper with the patient in person</u>

- Ensure the patient has had the opportunity to read the PIS and ask any questions they may have
- Check that the PIS version and date on the consent form correctly corresponds with the current full PIS. If a superseded version is stated, please update these details.
- Print the localised consent form
- Write the participant ID number on the consent form
- Ask the patient to complete the consent form by initialling all of the boxes, printing their name, date, and signing in the 'signature of participant' section
- If necessary, a witness completes the 'name of witness' section
- A delegated team member completes the 'name of person taking consent' section
- Find the participant's REDCap record; guidance on how to complete this can be found in section 22 (REDCap database)
- Once you are on the participant's Record Home Page, select the dot on the 'Participant Consent (Paper)' row
- Complete the *Participant Consent (Paper) instrument* and upload a copy of the consent form using the 'upload file' functionality, shown below

- Change the Form Status to 'Complete', and click 'Save and Exit Form'
- Please file the paper consent form as per your local procedures.

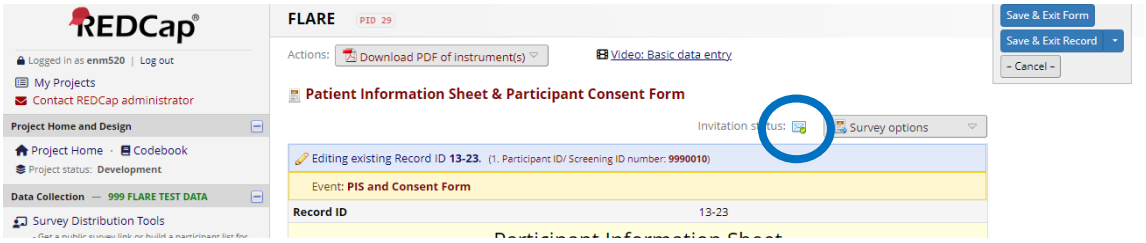


Obtaining informed consent remotely via email

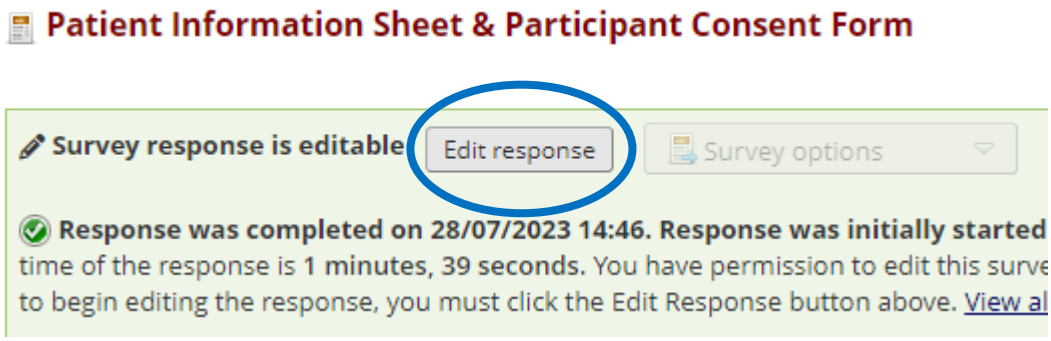
We suggest that if informed consent is obtained remotely via email, the patient is contacted by telephone to have the opportunity to discuss the study, ask any questions and obtain any guidance regarding completing the consent form.

1. Ensure the patient has had the opportunity to read the PIS and ask any questions they may have
2. Find the participant's REDCap record; guidance on how to complete this can be found in section 22 (REDCap database)
3. Once you are on the participant's Record Home Page, select the dot on the 'Patient Information Sheet & Participant Consent Form' row
4. Click on 'Survey options' in the top right side, and then select 'Compose survey invitation'.

5. Enter the patient's email address, and add in the subject line: 'FLARE Trial Consent Form to be completed'
6. Click 'Send Invitation'
7. A window will pop up, click 'Leave Page'
8. REDCap will then send the PIS and Participant Consent Form by email to the patient. You will know that the consent form has been successfully sent as the invitation icon will change to an envelope with a tick.



9. Once completed by the patient – click onto the '*Patient Information Sheet & Participant Consent Form' instrument*, and there will be message at the top stating that a survey response is editable. Select 'Edit response'



10. Enter your details in the 'Delegated person taking consent signature' section, and then click 'Save and Exit Form'. You will be asked to supply a reason for the data change. Enter 'confirmation of consent'.
11. Once the consent form has been completed, it can be viewed and downloaded via REDCap by clicking on the *Patient Information Sheet & Participant Consent Form instrument*, clicking on 'Download PDF of instrument(s)' from the top left side and selecting 'This survey with saved data (via browser's *Save as PDF*' option.
12. A PDF will load with the participant's, witness' (if applicable) and delegate's sections completed.

Post-consent tasks to be completed

- Provide copies of the localised PIS and completed consent form as follows:
  - 1 copy given to the patient by the site team (cannot be automated via REDCap).
  - 1 copy filed or uploaded into the patient's medical notes.
  - If a paper consent form is completed, please file as per your local procedures.
  - If you intend on completing the consent form electronically, please generate a file note to state that the completed consent forms are located in the main FLARE REDCap system.
- Complete the *Consent Status instrument* on REDCap.

- Record consent in the patient's medical records

Recording consent in medical records (for those eligible and consented)

Add a statement into the patient's medical notes documenting when the patient's eligibility was assessed, by whom and that the patient met the eligibility criteria, the patient had time to consider participation, ask questions, and went on to complete the consent form. Please document the version and date of the PIS and consent form used, along with the patient's participant ID.

Witness consent

Witness consent can be used for participants who are unable to document their voluntary participation due to their hand injury, or cannot read or write. In this scenario, the patient will be required to verbally agree to the statements on the consent form, with the witness and researcher present, and the witness will complete and sign the consent form on the participant's behalf, with the witness' details also recorded.

There is no requirement that this witness be impartial, and it may, therefore be the patient's family, friend, or be a member of the research team. Although it should be a different individual to the person taking informed consent from the patient.

Obtaining consent from a patient who does not speak English

We will not recruit patients who do not have adequate verbal or written English skills or do not have family or friends who can sufficiently support them in the completion of the questionnaire. This is because many of the outcome measures are patient completed scores that are not validated in languages other than English. It is therefore essential that the patient is able to communicate in English to sufficiently understand the patient reported outcome measures (PROMs). Where possible, interpreters can be used to facilitate understanding of the trial for non-English speaking participants for the purposes of the informed consent process only. In such circumstances, please document how consent was obtained in a *Comments instrument* on REDCap.

Patients who are eligible but decline to participate

- Add a statement into the patient's medical notes documenting their participant ID, when the patient's eligibility was assessed, by whom, and that the patient met the eligibility criteria but did not wish to participate.
- Complete the *Screening and eligibility instrument*
- Complete the *Consent status instrument*

6. Consent guidance and FAQ

This section is designed to guide the process of consenting patients, once a delegated surgeon has confirmed that the patient meets the initial screening eligibility criteria. This section does not represent all consent dialogue. Delivery of the information will need to be adapted to the individual patient. However, especially in surgical trials there is a lot more to this process, and the key to successful recruitment begins with this consent process. This guidance has been based on the GRANULE training. Further information about GRANULE training is available within this section.

According to the Good Clinical Practice guidelines the following should be explained to patients:

- Purpose of the trial
- Randomisation procedure
- Standard treatment
- Uncertainty of experimental treatments, their features and potential risks and benefits
- Right to withdraw from the research

Informed consent must be obtained prior to any baseline data collection or trial-related activities being undertaken. Giving consent is a voluntary and an ongoing process rather than a one-off procedure. Each subsequent time that the staff member has contact with the participant, their agreement to continue in the trial should be confirmed verbally.

<u>Key points to improving recruitment to clinical trials</u>

Burke and colleagues demonstrated that there are six key recommendations for improving recruitment to clinical trials and communication in recruitment consultations [1]:

- Know your patient population
- Provide clear summaries of the trial, supported with a published patient information leaflet
- Equipoise
- Elicit patient preferences and explore reasoning
- Understand and explain the randomisation process
- Seek recruitment training

To equip all recruiting staff members with this knowledge and initial practical skill set to recruit patients into a randomised controlled trial, the GRANULE course was developed, which is now hosted by the NIHR as an e-learning course. This is available via the following link: https://starsurg.org/granule/.

Completion of GRANULE training is not a FLARE trial training requirement but is encouraged to those who would benefit.

<u>Key points to remember before the recruitment consultation</u>

- **The FLARE trial has been identified as a priority by patients and consultants in the James Lind Alliance Priority Setting Partnership for hand conditions.**
- **Previous flexor tendon surgical repair trials have reported variations in patient outcomes [2-10].** These trials were likely underpowered and at a high risk of bias. **Therefore, there is no high quality evidence to inform clinical practice of whether the repair of FDP alone is as beneficial to the patient as the repair of both FDP and FDS.**
- The FLARE trial aims to generate this evidence to **facilitate surgeon and patient decision making.**

Addressing equipoise

As with many surgical trials we anticipate that equipoise will need to be addressed for the FLARE trial.

Personal equipoise

This is in relation to personal sense of equipoise; for example, a personal preference of which surgical repair to complete when both flexor tendons have been severed. See example discussion below of personal equipoise:

Repairing both FDP and FDS is a strong repair, why should we change this practice?

We know that the digit can function when FDP alone is repaired- I prefer this

Yes but the digit won't function as smooth as if both tendons were repaired

But if we only repair FDP, the repair will be less bulky and there will be less trauma to the surrounding tissue

The thing is, it is difficult to say that repair of FDP alone is as beneficial to the patient as the repair of both tendons; we don't have any evidence to inform clinical practice

Alternatively, being unable to communicate community equipoise, can unconsciously be reflected in the recruitment consultation and potentially bias the patient towards a particular repair.

It is important to recognise your own preferences, and to be careful not to provide your personal, or the community's, preferences when speaking with the patient about the trial.

Patient Equipoise

Patient equipoise can also be an important consideration. Guidance of how to maintain equipoise in discussion with the patient, is provided below.

Conveying Clinical Equipoise

Convey clinical equipoise by; acknowledging uncertainty, explaining the advantages and disadvantages of both treatments, and thinking 'balance' throughout the discussion.

These example messages may help when introducing the study to a patient to optimise consent:

a) BOTH types of surgery are COMMONLY used in the NHS to treat this injury. Neither are NEW treatments. Both WORK, but surgeons genuinely don't know if the repair of one tendon has the same benefits to the patient, as the repair of both tendons.

b) Taking part in this study is an opportunity to improve the future care of patients. This study will generate high quality evidence to inform both surgeon and patient decision making.

c) The patient's surgeon thinks they are suitable for the study and is happy for them to receive either surgical repair. Eligibility is checked in theatre. If at that point, the surgeon deems that the injury cannot be repaired by either trial surgery, the patient will not be randomised and the most appropriate repair will be undertaken.

d) Regardless of which type of repair the participant receives, the surgeon carrying out the operation is an expert.

Key points during the recruitment consultation

- **Provide a clear succinct summary of FLARE** to potential participants and **encourage questions** for all aspects of the trial and patient facing documents.
- **Tell the patient why they are eligible to participate**, what aspect of the surgical procedure will change, and what the expectations of their involvement are (e.g. frequency and nature of follow up).
- **Present a balanced view of both treatment options,** making it clear that there is currently no consensus, as both treatments are being practised within the NHS.
- **Ensure patient reaches and remains in a state of equipoise** i.e. no treatment preference.
- **Encourage questions and a conversation with the patient** and their relatives/carers if present.
- **Remember that eligible patients may be in pain,** and this can reduce their attention and make reading and understanding the information material difficult.
- **Allow the patient sufficient time to decide to make their decision.**

If the patient is willing to enter the study, ask them to complete the consent form. The consent form can be completed either in person (on paper or electronically) or remotely via email. Explain what will happen next.
If a patient needs more time to decide whether to take part, agree a time to be contacted with the patient.

Introduce yourself

Explain that you are part of the orthopaedic/plastic/therapy/research team and your role in the study.

Explain that they have been identified as a suitable candidate for a current study.

Provide a verbal summary of the study before presenting the patient information material to inform the patient of the trial details.

Discuss the full Patient Information Sheet (PIS)

- **Provide the patient with the PIS material and discuss each section as detailed.**
- **Discuss the randomisation process,** i.e. the surgeon does not choose the repair to complete, and include details of both treatment interventions.
- **Discuss the pros and cons of both treatment groups**, avoiding biased language.

Repair of FDP alone	Repair of FDP and FDS
• Commonly used in the NHS • Strong repair but possible reduced grip strength • Less scar tissue, which may make it possible to fully straighten the finger	• Commonly used in the NHS • Strong repair • More scar tissue which may make it impossible to fully straighten the finger

- **Try to maintain equipoise at all times,** by the end of your discussion the patient should acknowledge the advantages and disadvantages of both treatments.
- **Explain that the withdrawal from study participation does not need to be justified and will not affect the care that they receive.**
- **Explain what will happen if the patient does agree to take part,** such as assessment at surgery, follow-ups and expected time burden.
- **Encourage questions throughout.**
- **Check the patient has understood the information provided**, if needed ask that they repeat it back to you.

The patient should have time to discuss any information with the surgeon, family members or a member of the research team.

Describing randomisation

For patients to agree to take part in a randomised controlled trial, they need to 'make sense' of randomisation; what is the randomisation process? What is the purpose of randomisation? How does randomisation impact on their surgical treatment and future care? Whilst also emphasising that the patient has an equal chance to receive either treatment [10].

The staff member should be cautious to avoid gambling metaphors (e.g., 'flipping a coin'), as there is some evidence that these negatively affect patient consent to trials. Avoid using the word 'random' for treatment allocation as patients have stated this suggests that 'staff don't really care'. Instead, explain that treatments will be allocated 'fairly' to give us 'comparable' groups of patients. Below is a suggestion of how to present randomisation to patients:

"If you agree to take part in the study, you will be allocated to a treatment group by a process called randomisation. This is the fairest method to produce two groups of patients who are similar in every respect – for example age and gender. I can't choose and you can't choose your treatment, so there will be no bias. One group has both tendons repaired and the other group has a single tendon repaired. Because the groups will be 'balanced', at the end of the study we can fairly compare them to see whether one treatment is as good as the other without worrying that other factors (such as age or gender) have influenced the outcome."

Managing Patient Preferences

It is important to recognise that a patient may have treatment preferences; if so, try to understand why the patient has that preference, acknowledge the rationale, provide a balanced view of both treatments tailored to their concerns, and encourage the patient to keep an open mind.

Examples consent discussions for FLARE

Bad examples

'Hello, my name is Mr X I am the consultant surgeon who will be treating you for your tendon injury. Your injury is going to require surgery to fix the severed tendons. We here at XX hospital have always repaired both tendons to treat this injury with very successful outcomes which we are happy with. There is a research trial at the moment that we are taking part in to look at a similar repair, if you took part a toss of the coin would decide whether we repair one or both of your tendons.'

'Hello, my name is Ms T I am the consultant surgeon and will be treating you for your finger injury. I have recently started repairing one tendon instead of both tendons. There is a research trial taking place to compare the repair of one tendon against the repair of both tendons, but I don't think that would be best for you.'

Good examples

'Hello my name is Ms Y I am the consultant surgeon who will be treating your finger injury. We have discussed your treatment at the trauma meeting here at the hospital and we felt that the best option is for you to have surgery. There are two different techniques that we could use during the surgery to repair the tendons in your finger. One is the repair of one tendon only, and the other is the repair of both tendons.

At the moment, although both of these techniques are in use in the NHS, we do not know if the repair of one tendon is as beneficial to the patient as the repair of both tendons, because they haven't been compared with each other in research. So that is why we are taking part in the trial to compare one with the other. I am very comfortable with you having either of the surgical treatments.'

Frequently Asked Questions during consent

Q: I would rather have [specified surgical repair]

A: I understand why you would think that [specified surgical repair] could be better, but we do not know this because it has not yet been tested in a large trial. Both surgical repairs have been in use in the NHS as standard care for many years.

Q: I am not keen on not knowing which treatment I receive.

A: Ordinarily after surgery you may not be told the exact surgical repair that has been used to repair your finger. The type of repair does not change any of the rehabilitation or aftercare that you will receive.

Q: Why would I no longer take part when I go to surgery?

A: At surgery your injury will have a more in-depth review to see if it meets the criteria needed to continue in the trial. The surgeon will check that both tendons are severed and your injury continues to meet the entry criteria. If your injury does not meet the criteria, your treatment will be decided by the surgeon, and you would not be able to continue in the trial.

Q: Would you take part?

A: Having not had this injury it is difficult to answer but there are other hand surgery trials running throughout the NHS as we speak, and patients agree to take part.

Note: It is important at this stage not to try and avoid the question as this will appear that the consent taker would not agree to take part.

Q: If I didn't take part in the trial, which repair would you complete?

A: Every injury is unique and so I won't know how to repair your injury until we are in theatre where I can have a more in-depth look.

Further Useful Reading/References

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3. Tang, J.B., Flexor tendon repair in zone 2C. The Journal of Hand Surgery: British & European Volume, 1994. 19(1): p. 72-75.
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5. Sadek, A.F., Flexor digitorum profundus with or without flexor digitorum superficialis tendon repair in acute Zone 2B injuries. J Hand Surg Eur Vol, 2020. 45(10): p. 1034-1044.
6. Lebot, G., et al., Medium-term clinical outcomes of Zone 2B/2C finger flexor tendon repairs: influence of management of flexor digitorum superficialis. Journal of Hand Surgery (European Volume). 0(0): p. 17531934221102666.
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8. Paillard, P.J., et al., Gliding resistance after FDP and FDS tendon repair in zone II: an in vitro study. Acta Orthop Scand, 2002. 73(4): p. 465-70.
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10. Pan, Z.J., et al., Outcomes of 200 digital flexor tendon repairs using updated protocols and 30 repairs using an old protocol: experience over 7 years. J Hand Surg Eur Vol, 2020. 45(1): p. 56-63.

11. Scantlebury, A., et al., Embedding qualitative research in randomised controlled trials to improve recruitment: findings from two recruitment optimisation studies of orthopaedic surgical trials. BioMed Central Trials, 2021. 22(461)
12. Wade J, Donovan JL, Athene LJ, Neal DE, Hamdy FC. It's not just what you say, it's also how you say it: Opening the 'black box' of informed consent appointments in randomised controlled trials. Social Science & Medicine 2009; 68(11):2018-28.

7. Baseline data collection

The following REDCap instruments need to be completed at baseline (after consent and prior to randomisation):

1. Screening And Eligibility
2. One of the following:
   - Patient Information Sheet & Participant Consent Form
   - Participant Consent (Paper)
3. Consent Status
4. Patient Baseline Questionnaire
5. Baseline Investigator
6. Contact Details

Please check that all of the above instruments are fully completed with no missing data prior to surgery, and their form statuses are saved as 'complete'.

There are various ways in which a patient could complete the Patient Baseline Questionnaire, including;

Patient Baseline Questionnaire completed by email

To send the *Patient Baseline Questionnaire instrument* by email, please complete the following steps:

- Find the participant's REDCap record; guidance on how to complete this can be found in section 22 (REDCap database)
- Once you are on the participant's Record Home Page, select the dot on the 'Patient Baseline Questionnaire' row
- Click on 'Survey options' and then select 'Compose survey invitation'
- Enter the patient's email address and change the Subject to; 'FLARE Trial Patient Baseline Questionnaire to be completed'
- Copy and paste the following text into the text box before the survey links provided by REDCap. Do not delete the links provided by REDCap;
  'Thank you for agreeing to take part in the FLexor repAir and REhabilitation (FLARE) Trial. Your participation in this study will help to find out the best method to repair flexor tendon injuries like yours in the future. We appreciate your help with this study and thank you for taking part.
  Please find below a link to the initial baseline questionnaire which you have agreed to complete. We hope it will take no longer than about fifteen minutes of your time to fill in. We would be very grateful if you could complete the questionnaire before you attend the hospital for surgery.
  If you have any questions or concerns relating to completion of the questionnaire or taking part in the study, please contact us using the contact details provided in the patient information sheet.'
- Click 'Send Invitation' and then 'Leave Page'
- Once the patient has completed the baseline questionnaire, their answers will appear in the *Patient Baseline Questionnaire instrument* and the form status will automatically be changed to complete (green dot with a tick)

Patient Baseline Questionnaire completed electronically, in person while at site

Patients can complete the *Patient Baseline Questionnaire* with a staff member logged into REDCap if a portable device is available.

Please be aware that if there is an unstable internet connection, REDCap will still be able to save the data captured whilst offline.

Patient Baseline Questionnaire completed on paper at site

If the patient prefers to complete the *Patient Baseline Questionnaire* on paper, the site team are responsible for printing and providing this. A PDF of the *Patient Baseline Questionnaire* is available within your FLARE eISF. **Please check that the questionnaire is fully completed while the patient is at site (prior to randomisation).** Site staff will then need to accurately enter the data on REDCap, check the responses on REDCap match those on paper, and ensure the information is saved and the instrument is marked as completed. Please file the paper copy of the *Patient Baseline Questionnaire* in the ISF.

Patient Baseline Questionnaire key points

- If a Patient Baseline Questionnaire is completed on paper, please enter the data onto REDCap before the patient presents to surgery, to reflect that the data collection was completed before randomisation.
- If the patient is struggling to answer the Patient Related Wrist/Hand Evaluation post injury questions, due to experiencing the injury for a limited period of time, please encourage them to provide an estimate of the impact/experience of their injury in relation to the question, rather than leaving it blank.

Contact Details instrument

The *Contact Details instrument* captures the patient's contact details and preferred contact method (e.g. phone, email or post) to be used for questionnaire follow up purposes.

Please check with the patient during clinical follow up visits whether their contact details have recently changed.

8. Eligibility assessment at surgery and randomisation

Eligibility assessment at surgery

At surgery, a delegated surgeon reassesses the participant's eligibility, either in person or remotely, against the trial eligibility criteria.

Please note that a non-delegated surgeon cannot complete the patient's intraoperative eligibility assessment.

Further clarification to assist with application of the inclusion/exclusion criteria is given in Table 4.

Table 4: Eligibility criteria at randomisation

The answer to ALL inclusion criteria must be YES for the patient to be eligible	
Inclusion criteria	***Clarification***
Complete division of FDP and FDS in Zone 2 of a single finger	In order to answer the clinical question of whether repairing one or both flexor tendons in zone 2 of the digit, we need to include only patients with both tendons divided. **If a patient has a multiple digit injury, please investigate all injured digits prior to randomisation to ensure that there is only one digit with both tendons severed.** Flexor tendon injuries in zone 2 are difficult to treat from a surgical perspective and their outcome is often difficult to predict and there is no high-quality evidence in the literature which describes which method is best. A single digit allows for accurate assessment of outcome for that digit without the confounding effect form an additional digital injury.
Injury amenable to primary repair	The treatment methods and outcomes for flexor tendon injuries that require delayed or reconstructive surgery cannot be compared with injuries amenable to primary repair as the surgical interventions and outcomes differ. If the injury is old (e.g. 2 weeks), the patient remains eligible for participation on the provision that the surgeon treating the patient can get adequate apposition of the tendon ends.

The answer to ALL exclusion criteria must be NO for the patient to be eligible	
Exclusion criteria	***Clarification***
Injuries with loss of tendon substance or skin necessitating reconstruction	Injuries requiring tendon or soft tissue reconstruction will be expected to have different outcomes and rehabilitation potential when compared to injuries without tendon substance or skin loss and cannot be directly compared to the study population.
Division of both digital arteries resulting in revascularisation of injured digit	Any injury requiring revascularisation of a digit is a major insult to a digit and the outcomes from this

	type of injury cannot be directly compared to our study population.
Division of both digital nerves	Division of both digital nerves suggests a significant injury to a digit and will require additional surgical exploration and exposure of the digit making the injury incompatible for comparison with our study group. A single nerve injury can be included.

- **If the patient is eligible,** continue on to randomisation.
- **If the patient is not eligible**, the patient receives standard care.
- **If the patient attends for surgery, however, expresses that they no longer want to be involved in the FLARE Trial,** the patient receives standard care.
- Complete the *Eligibility and Randomisation instrument* on REDCap for all patients.

! To remove the need to descrub and complete REDCap data entry, the delegated surgeon can complete the eligibility assessment in surgery, whilst an unblinded delegated colleague is completing the REDCap data input and randomisation either in person or remotely.

! If the patient has a multiple digit injury, please check all injured digits intraoperatively to ensure that the injury still meets the multiple digit eligibility criteria.

Remote completion of the intraoperative eligibility assessment

Delegated (study) surgeons can complete the intraoperative eligibility assessment remotely with the operating surgeon if they are not included on the trial delegation log. In this scenario, please ensure the following:

- Each eligibility criterion should be discussed and confirmed.
- Multiple digit injuries: examine all injured digits and confirm that only one digit has both FDS and FDP tendons completely severed.

If the patient is eligible and will be randomised, please ensure that:

- The operating surgeon is made aware of all trial blinding requirements; that they cannot inform the patient of which tendons are being repaired, and to be mindful when communicating the surgical procedure to their colleagues whilst in theatre, and subsequent communications with therapy team and GP.
- The operation note remains blinded as per guidance in section 11. Blinding procedure.

Randomisation and Surgical data entry into REDCap:

- This will need to be performed by a member of the study team that has the appropriate access rights.

- When completing Question 2 ‘Name of delegated surgeon confirming eligibility’ within the Eligibility and Randomisation instrument, enter the name of the delegated surgeon, and not the operating surgeon.

9. Intraoperative Eligibility Questions and Answers

Q: Would a pre-existing motor impairment of the hand from a previous spinal injury make the patient ineligible for the trial?

A: Yes, a pre-existing motor deficit in the digit would make them ineligible.

Q: A colleague repairs FDP and FDS when he would usually only repair one slip of FDS and excise the other to prevent the repair being too bulky. Would this still be classed as FDP and FDS repair, and be accepted for inclusion in the FLARE trial?

A: Repair of a single slip of FDS is acceptable and would need to be recorded on REDCap.

10. Randomisation

Once you have completed the *Eligibility and Randomisation instrument,* please click on the *Prerandomisation Final Check instrument*, change the Form Status to 'complete' and click 'Save and Exit Form'. This will trigger REDCap to randomise the participant. No data entry is required within the *Prerandomisation Final Check instrument*.

The *Randomisation Data instrument* dot will automatically change to green, and the treatment allocation can be viewed within this instrument.

For further information on how to complete randomisation on REDCap, please refer to section 22 where screenshots of this process are available.

Please be aware that REDCap requires internet connection in order to randomise.

! To remove the need to descrub and complete randomisation on REDCap, the delegated surgeon can complete the eligibility assessment in surgery, whilst an unblinded, delegated colleague is completing the REDCap data input and randomisation either in person or remotely.

11. Blinding procedure

Table 5 clarifies which individuals are blinded to the treatment allocation and surgical technical information, and which documentation to consider with respect to patient and site staff blinding. Trial participants will be blinded to the treatment allocation up to the last follow up point i.e., six months from the date of randomisation.

Once the participant has completed their six month follow up, YTU will contact the site to unblind the participant's medical records by filing or uploading a copy of the *Randomisation Data* and *Primary Surgery instruments* (from REDCap) into their medical records.

Table 5: Trial staff and documentation blinding

Person	Blinded?	Suggested documents that require the treatment to be blinded*
Patient	Yes	- Discharge letter - Hand therapist advice
General Practitioner	Yes	- GP letters and correspondence - Discharge letter
Blinded hand therapy, clinical and research teams	Yes	- Operation note - Medical notes - Referral to hand therapy
Blinded surgeon (not involved in participant's randomisation or surgery)	Yes	- Operation note - Medical notes
Unblinded surgical, clinical and research teams	No	Not applicable
YTU trial statisticians	No	Not applicable
YTU and central research team	No	Not applicable

* Please consider if there are any other documents/systems that your site use which may require the treatment allocation and surgical procedure information to be blinded.

<u>Communicating blinding statements in clinical documentation/notes</u>

Completing the operation note / referral to hand therapy / discharge letter

To document the surgical procedure, the surgeon can write the following information into the operation note:

- Flexor tendon repair performed as per FLARE trial
- Information about pulley repair or venting e.g. 'A2 pulley vented'
- Nerve repair e.g. 'radial nerve repaired'
- Statement about quality of repair e.g. 'tendon repair acceptable for any preferred therapy regimen'

All remaining surgical information documented in the *Primary Surgery instrument*, as well as the treatment allocation, must be blinded in the operation note until the participant has completed their 6 month follow up questionnaire.

Any details about the operation that are not collected on the *Primary Surgery instrument* can be recorded in the medical notes.

In the operation note, we suggest adding a statement advising who to contact should the participant's treatment allocation need to be unblinded (e.g., to contact either a delegated site

surgeon or email the YTU team (ytu-flare-trial@york.ac.uk) with the participant ID number (no identifiable information specified)).

Unblinding procedure for medical necessity

If the clinical team need to know the treatment received, they can find out by contacting either a delegated surgeon or emailing the YTU team (ytu-flare-trial@york.ac.uk) with the participant ID number (no identifiable information);

If they contact a delegated site surgeon, the surgeon can access the treatment allocation via REDCap and notify the clinical team of which treatment was allocated. Please document unblinding in a *Comments instrument* on REDCap and ensure the reason unblinding was required is recorded.

If they email the YTU team, the YTU team will email a response to the clinical team with confirmation of which treatment was allocated. The YTU team will respond within office working hours, Monday - Friday. Please ensure the unblinding request email details the reason unblinding is required. Please document unblinding in a *Comments instrument* on REDCap and ensure the reason unblinding was required is recorded.

Accidental unblinding

If a member of the site team or a participant is accidentally unblinded to a participant's treatment allocation, please notify the YTU team and document in a *Comments instrument* on REDCap, details such as;

- The date accidental unblinding occurred
- Whether site team member(s) or the participant has been unblinded
- Reason accidental unblinding occurred
- Corrective and preventive measures being actioned to avoid future incidents of accidental unblinding

12. Post surgical activities

After completion of the participant's surgical repair, the following tasks need to be completed by the site team:

All patients

- Document in the patient's medical records that the eligibility assessment for randomisation was completed, by whom and when, and whether the patient was found to be eligible or ineligible.
- Verbally inform the patient of whether they continue on the FLARE Trial or not.

Eligible participants

- Complete the *Primary Surgery instrument* on REDCap.
- The *FLARE Participation Letter/Email - Eligible* is given/emailed/posted to the participant.
- Send a *FLARE GP Letter* to the participant's GP.
- Add a blinded statement into the patient's medical notes about the surgical procedure (please refer to section 11 (Blinding procedure) for further details).

Ineligible patients

- You do not need to complete the *Change of Status instrument* on REDCap.

13. Completing follow-up visits

Please note that blinded members of the surgical team can complete follow-up activities, provided they have not been involved with the participant's randomisation and surgery and are not informed of the treatment allocation.

Do not communicate the treatment allocation to the participant, blinded research site members, nor hand therapists/physiotherapists involved in the follow up activities.

- Please complete the *Investigator Form instrument* at the visit for the relevant timepoint.

- Finger Range Of Motion (ROM) measurements should be obtained at the 6 week and 3 month visits. We encourage the 3 month visit to be completed in clinic where possible, to enable grip strength measurements to also be obtained.
  For instructions on how to complete finger ROM and grip strength measurements, please refer to section 16 (Hand Rehabilitation, Finger Range of Motion and Grip Strength)

- If necessary, please also complete the following instruments on REDCap;
  - *(S)AE*
  - *(S)AE Follow-up*
  - *Comments*
  - *Additional surgery*

- Should you be made aware of the participant changing their home address, email address or telephone number, please ensure the *Contact details instrument* on REDCap is updated.

- YTU will contact the participant at the 6 week, 3 month and 6 month timepoints to complete their *Follow Up Questionnaire* by email/post/phone.

Follow Up Frequently Asked Questions

Q: An error message appears on REDCap when entering hyperextension, to say that the number is outside of the expected range; what do I do?
A: Ignore the error message, enter hypertension as -XXX and save and complete the form. No data will be lost.

Q: A participant is being referred to a neighbouring Trust for follow up with the hand therapy team, how do we collect the follow up data?
A: Please complete the follow up data collection for these participants, either in person or remotely. Please note that participants will not receive travel expenses for attending follow up appointments in person.

14. 6 months post-surgery

The following tasks should be completed once the participant has returned their 6 month follow up questionnaire.

Site team tasks

Please complete the following tasks once notified by the YTU team;

- Upload/file a copy of the *Randomisation Data* and *Primary Surgery instruments* into the patient's medical records. Please refer to subheading 'Printing REDCap instruments with saved data as a PDF' within section 22 of this Manual for guidance on how to complete this.

- Review the participant's medical records to check if any complications, Adverse Events, Serious Adverse Events or additional surgeries have occurred since the 3 month visit. If so, please record these on REDCap. If there are no events or additional surgical procedures to record, please confirm this via email correspondence with the YTU team.

YTU tasks

- Send the participant a letter to inform them of which surgical treatment they received.

- Send the participant a £10 reward as a thank you for completing the 6 month patient questionnaire, as a minimum.

- Contact site to advise that the *Patient 6 month Follow Up Questionnaire* has been completed and to request the site upload/file a copy of the *Randomisation Data* and *Primary Surgery instruments* into the patient's medical records.

- FLARE qualitative researcher will contact 40 participants, if they consented to be contacted, to invite them to participate in a qualitative interview.

- Send trial results when available if the participant requested this information.

15. Other REDCap instruments

Comments instrument

To be used for capturing any additional details that you have not been able to add to the relevant REDCap instrument, such as anomalies in data, unblinding (accidental and if due to medical necessity), visits completed outside of the visit window, and deviations relating to data (e.g., missed visits, providing further information regarding why data are missing). **Please do not record patient identifiable information here.**

If you are unsure of whether something should be recorded in the *Comments instrument*, please contact the YTU team, specifying the participant ID number.

Additional Surgery instrument

The *Additional Surgery Instrument* should be completed in REDCap if a participant has a surgical procedure on their affected digit between 3-6 months post-randomisation. If there are no events to record, please confirm this via email correspondence with the YTU team.

Principal Investigator Sign Off instrument

This should be completed by the site PI at the end of the trial (one per participant). YTU will contact the PI to advise when this should be actioned.

16. Hand Rehabilitation, Finger Range of Motion and Grip Strength

Hand Therapy/Occupational Therapy Clinic Follow ups

For both treatment groups, the FLARE Trial will not determine any requirements of which splint is used or what the hand therapy regimen entails. These rehabilitation activities will be determined by the participant and hand therapist based on usual practice at the participating site.

Finger Range of Motion (ROM) Data Collection

Equipment: One goniometer. Please use the JAMAR Finger/Toe Goniometer for finger ROM data collection. Example is below in Figure 1.

Figure 1: JAMAR Finger/Toe Goniometer

Data Input: All measures should be entered into the relevant REDCap instrument; *Investigator Form- 6 week* or *Investigator Form- 3 months instruments* on REDCap.

Position: For all flexion and extension measures, the wrist should be positioned in neutral or slight extension, with the elbow resting on a table or other surface. The goniometer should be positioned or aligned dorsally.

Measurement order: Capture ROM measurements for the affected finger first. Measure the metacarpophalangeal joint (MCPJ) first, then the proximal interphalangeal joint (PIPJ), and finally the distal interphalangeal joint (DIPJ) in extension, then repeat the order in flexion. Repeat this procedure for the same finger on the contralateral hand.

If you can't measure the contralateral finger (e.g. it's missing or also injured), please record measurements of the neighbouring on the contralateral hand as a surrogate. If a contralateral measurement is not possible, document this in the respective Investigator instrument.

If completing the ROM measurements via remote consultation, please following these steps:

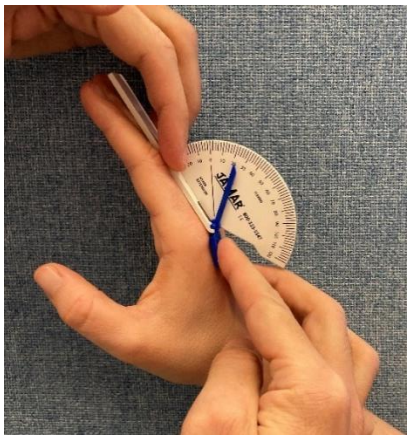
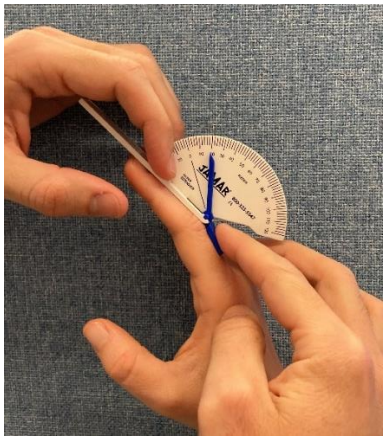
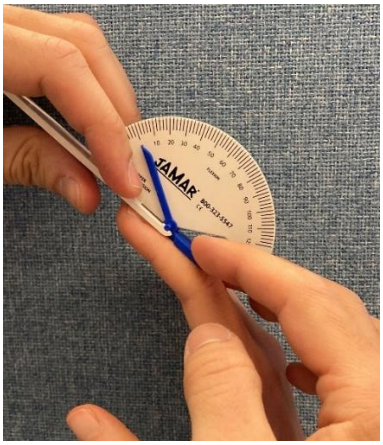
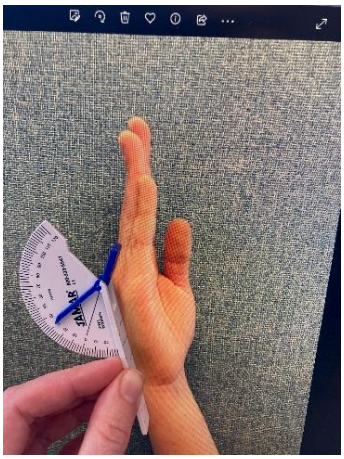
1. Check that the participant is happy for you to take the screenshot and advised that it will be deleted once data collection is completed.
2. Ask the participant to hold their hand and fingers still so that a lateral view of the target finger from an ulnar or radial perspective is achieved to best visualise the affected finger, and the dorsum of the finger is visible on the screen i.e. not blocked by other digits.
3. Capture the screenshot by holding down 'Ctrl', 'Alt' and 'PrtScn' on your keyboard.
4. Complete the same process again for the digit being measured on the contralateral hand, if possible.
5. Measure ROM for all joints of the affected finger and for the same finger on the contralateral hand (guidance below).
6. Record the measurements onto the respective Investigator instrument.
7. Delete the screenshots.

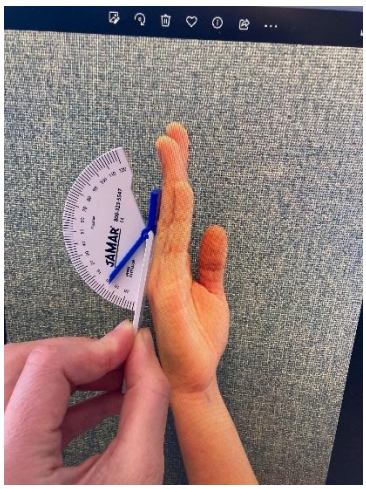
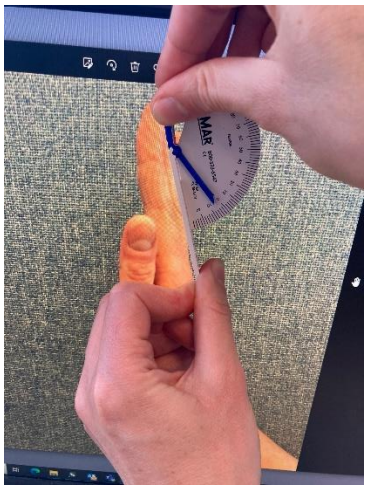
Extension ROM measurements for all joints (MCPJ, PIPJ, DIPJ)

1. For in person measurements, position the static (long) arm distal to the joint being measured.
2. For virtual measurements, position the goniometer in the opposite orientation i.e. with the static (long) arm proximal to the joint being measured.

See Table 6 below for examples of extension ROM measurements being collected.

Table 6: In Person Extension Measurements

In Person Extension Measurements		
MCPJ	**PIPJ**	**DIPJ**
		
Virtual Extension Measurements		
MCPJ- Radial	**MCPJ- Ulnar**	**PIPJ - Radial**
		
PIPJ - Ulnar	**DIPJ – Radial**	**DIPJ – Ulnar**

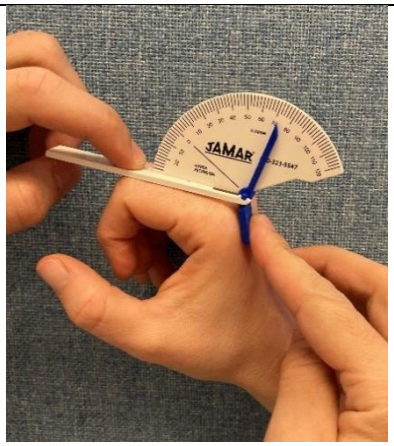
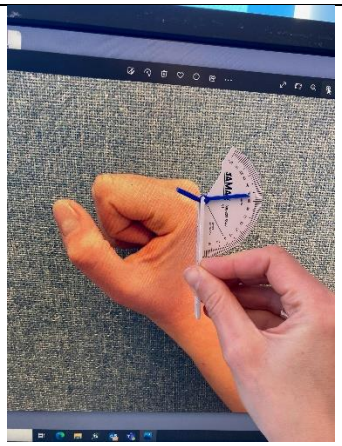
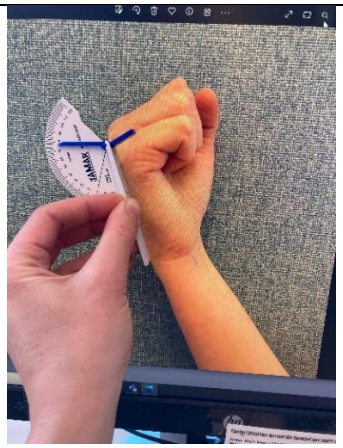

Flexion ROM measurements

MCPJ

- For in-person measurements, align the static (long) arm of the goniometer with the dorsum of the proximal phalanx and the dynamic (short) arm with the dorsum of the metacarpal.
- For virtual measurements, position the goniometer in the opposite orientation, i.e. align the static (long) arm of the goniometer with dorsum of the metacarpal.

See Table 7 below for examples of flexion ROM measurements being collected for MCPJ.

Table 7: Flexion ROM measurements for MCPJ

In Person- MCPJ Flexion Data Collection	**Virtual- MCP Flexion Data Collection**	
MCPJ	**MCPJ - Radial**	**MCPJ - Ulnar**
		

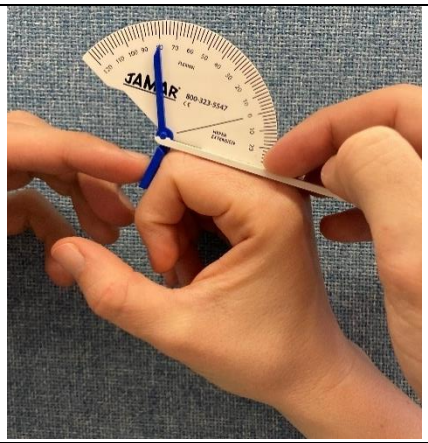
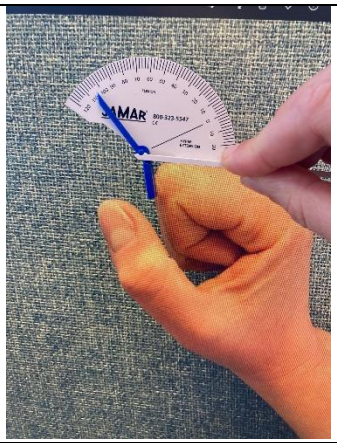
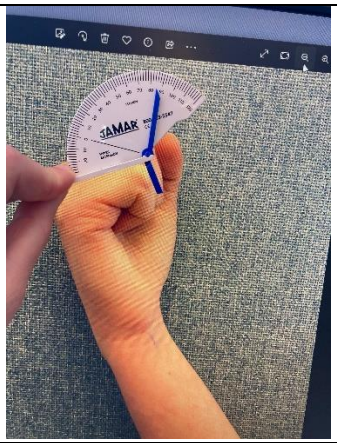
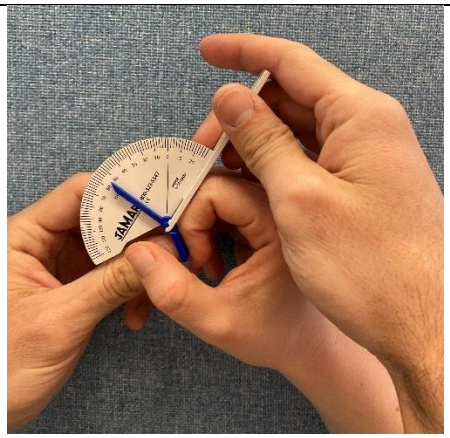
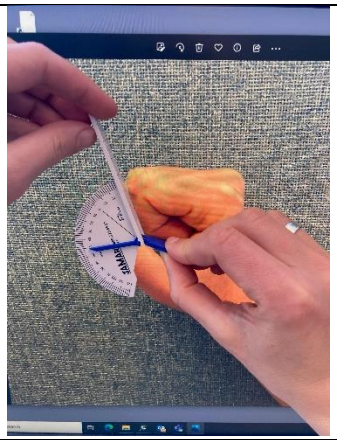
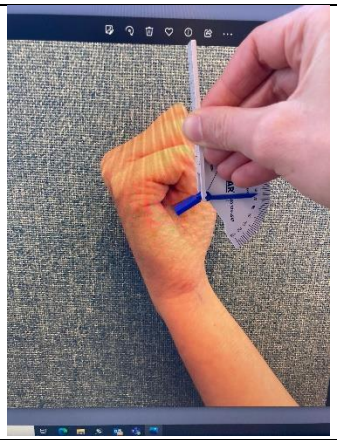
PIPJ and DIPJ

For virtual and in-person flexion measurements:

1. Align the static (long) arm of the goniometer proximal to the joint being measured and position the dynamic (short) arm distally.

See Table 8 below for examples of flexion ROM measurements being collected for PIPJ and DIPJ.

Table 8: Flexion ROM measurements for PIPJ and DIPJ

In Person- PIPJ Flexion Data Collection	**Virtual- PIPJ Flexion Data Collection**	
PIPJ	**PIPJ – Radial**	**PIPJ – Ulnar**
		
In Person- DIPJ Flexion Data Collection	**Virtual- DIPJ Flexion Data Collection**	
DIPJ	**DIPJ – Radial**	**DIPJ- Ulnar**
		

If you do not have access to a goniometer and have notified the YTU team of this during the set up process, please leave Section B of the *Investigator Form- 6 Weeks* or *Investigator Form- 3 months* blank and complete a *Comments instrument* to document that ROM data collection was not completed due to the site not having access to a goniometer.

Grip Strength Data Collection

Preparations before using the Dynamometer

1. Clean the dynamometer handle
2. Make sure the Peak-Hold Needle is set to '0' by turning the Peak-Hold Knob; see Figure 2 below
3. Make sure the handle slot is in position 2; see Figure 3 below

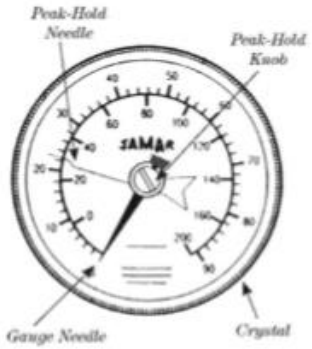


Figure 2: Dynamometer dial

Figure 3: Dynamometer handle slots

Measuring Grip Strength with Dynamometer

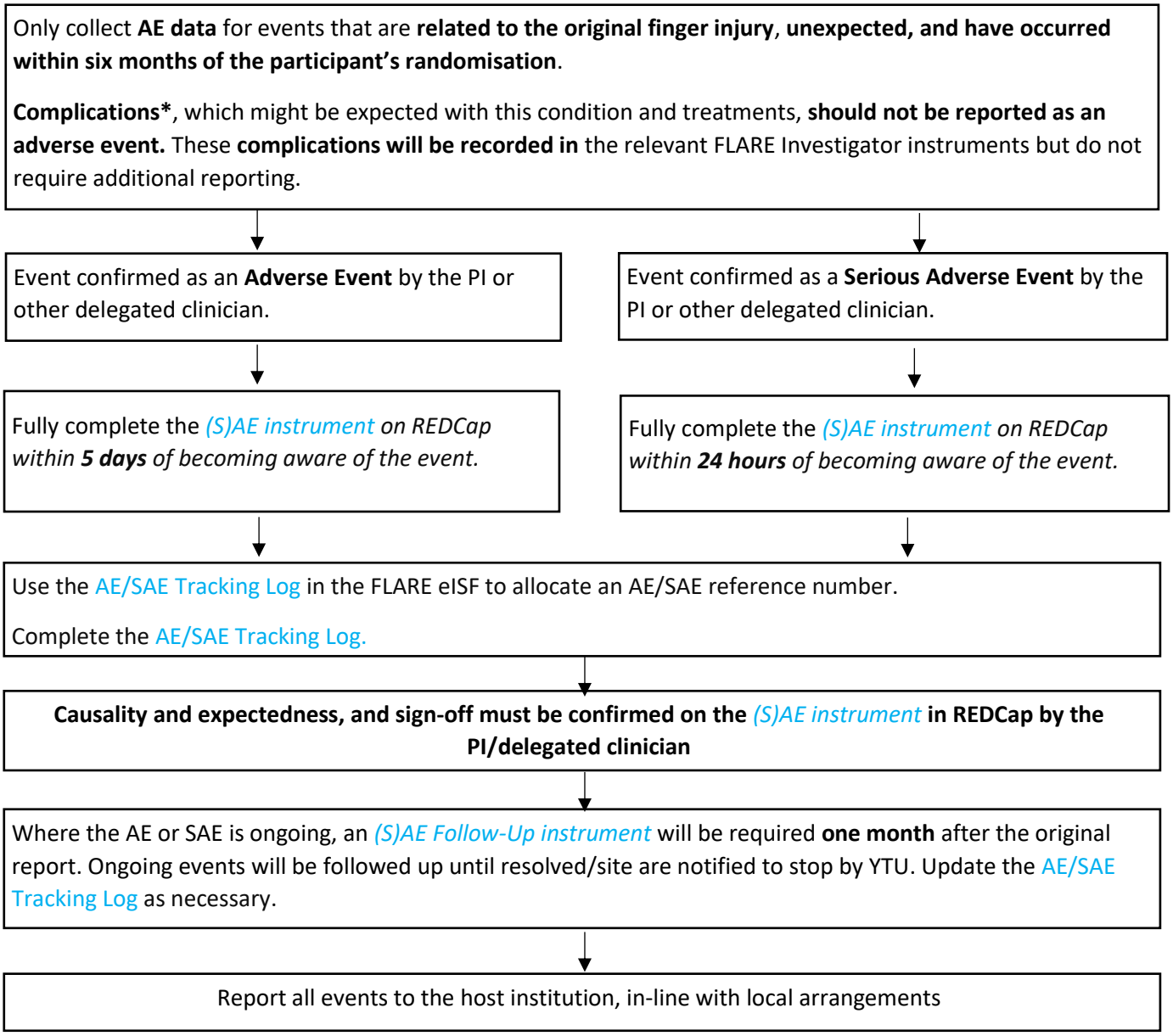
- Test the unaffected hand first.
- Make sure the participant is in a comfortable sitting position with their shoulder adducted and neutrally rotated, and feet flat on the floor.
- The elbow should be kept as close to 90 degrees as possible and not resting on the table or arm of the chair.
  The forearm should be in a neutral position (mid-prone) with the wrist in 0-30 degrees extension, and 0-15 degrees ulnar deviation
- Ask the participant to put their hand through the wrist strap (if available).
- Instruct the participant to grip the hand dynamometer with their fingers around the handle with the readout dial pointing away from their body.
- To start the test, instruct the participant to grip the dynamometer as hard as they can for 4-5 seconds and relax. The assessor should say "Squeeze as hard as you can…harder…harder…relax."
- Once the participant has relaxed their hand, record to the nearest kilograms (kg), indicated by the Peak-Hold Needle, onto the *Investigator Form- 3 Months instrument* on REDCap.
- After completing one grip strength recording, complete the same assessment process on the other hand.
- Complete a total of three grip strength measures per hand, alternating hands between readings.

If the 3 month follow up does not take place in person and grip strength data collection was not completed, please leave Section C of the *Investigator Form- 3 months* blank and complete a *Comments instrument* to document that grip strength data collection was not completed due to the follow up visit taking place remotely.

17. Adverse Event reporting

If you are unsure whether an event should be reported as an Adverse Event (AE) or Serious Adverse Event (SAE), please contact the YTU team prior to reporting.

Please refer to the FLARE trial protocol for more information regarding collecting, recording, and reporting AEs/SAEs. Please note that AEs and SAEs should be reported for both treatment allocation groups of the trial.



Please note:

- When events occur concurrently, they should be recorded as separate events (i.e., complete separate *(S)AE instruments* in REDCap in the case of multiple concurrent AEs/SAEs).
- Any complication or Adverse Event may change over time to meet the criteria for being serious. At this point, it should be treated as a *Serious Adverse Event.*

* Expected complications

Table 9. Additional clarification regarding expected complications associated within flexor tendon repair surgery.

Complication	Clarification
General surgical complications	
Deep wound infection	An infection involving the flexor sheath of the digit or palm or a deep space infection requiring further operative intervention
Bleeding /haematoma	
Surgical site infection	
Delayed wound healing / wound dehiscence	
Tourniquet related nerve injury	
Superficial infection	Skin infection that may require antibiotic treatment but does not require further surgical intervention
Suture abscess	Localised pus around a suture
Rehospitalisation	Relating to the original injury only
Unexplained pain	
Anaesthetic-related complications	
Myocardial infarction (MI)	
Cerebrovascular accident (CVA)	
Venous thromboembolism (VTE)	
Block related nerve lesion	Persistent nerve dysfunction after the expected time period for the regional block to wear off i.e.,>48 hours
Local anaesthetic toxicity	
Complications specific to flexor tendon repair surgery	
Digital nerve injury / neuroma / numbness / altered sensation	
Re-rupture of tendon repair	
Bow stringing	
Joint stiffness	
Tendon adhesions	
Cold intolerance	
Complex regional pain syndrome	Excess and prolonged pain and inflammation following the flexor tendon injury associated with changes in skin colour, temperature and swelling
Hand therapy-related complications	
Skin problems related to splint fitting	

18. Protocol deviations, violations, and breaches

An event is identified which is deemed to be a protocol deviation, violation, or breach.

↓

Contact YTU immediately by email (ytu-flare-trial@york.ac.uk) or phone to advise of the circumstances in relation to the event.

↓

YTU will advise whether a file note or *Comments instrument* should be completed on REDCap to provide further details of the protocol deviation/violation/breach, and any corrective/preventative actions taken. Generally, a *Comments instrument* should be completed if the deviation/violation/breach relates to data and/or an individual patient only; whereas a file note will be requested if the incident affects more widely.

Ensure the participant is referred to by their participant ID number, and no identifiable information is included.

Should you be asked to complete a file note, please allocate a file note number by completing the file note log (available in your eISF). Please send a copy of the file note to YTU at ytu-flare-trial@york.ac.uk

↓

YTU will review the event and will advise if any further action is required.

↓

YTU will arrange to report events to the Sponsor if required.

The Sponsor will arrange to report the event to the REC if required.

19. Participant change of status

A participant can choose to withdraw at any stage without giving a reason. If possible, we would still like to collect some data from patients who are unable/unwilling to complete all trial activities. Therefore, please discuss options with participants about withdrawal from study specific activities; for example, no longer complete questionnaires or hospital visits but will allow you to review medical records, or complete 6 week and 3-month clinic visit remotely.

Please ensure the *Change of Status instrument* is completed on REDCap.

Please also complete a *(S)AE instrument* on REDCap if the participant has died and the death is within 6 months of treatment, or if related to the original injury, or an aspect of taking part in the study.

Please note, if a change of status form is completed to say the participant has died or fully withdrawn, no other data collection forms will be available to complete. Please ensure you complete any other data collected prior to completing the *Change of Status instrument.*

The *Change of Status instrument* is a repeating instrument and can be completed multiple times if required.

20. Collaborator agreement and points system

This information sheet details the agreement between YTU and FLARE trial collaborators (non-author contributors).

- YTU recognises the NIHR Associate PI (API) scheme and values the role trainees and collaborators can have in research.
- YTU seeks to involve APIs and collaborators in studies where possible.
- YTU, alongside site staff and R&D departments, commits to provide evidence for trainees and/or consultants of their participation in studies as part of Continuing Professional Development (CPD).
- YTU recognises the International Committee of Medical Journal Editors requirements for authorship[1] and the statement from the National Research Collaborative & the Association of Surgeons in Training.
- YTU intends to name individuals who can demonstrate these criteria as collaborators on a submitted manuscript. This will be subject to journal policy.
- Collaborators will only be acknowledged in the main/one clinical paper.

To achieve collaborator status and become a PubMed searchable FLARE collaborator, an individual must obtain a minimum of 10 points based on the following criteria;

Activity	Points	Evidence/ suggestions
Completion of NIHR API Scheme	7	API certificate
Completed Study Specific Training as per delegated responsibilities	1	Completed Study Specific Training evident by certificates when joining the study
Screening	2 (per patient)	Completed *Screening and Eligibility instrument* on REDCap
Consent	1 (per patient)	Completed consent form
Randomisation/operation	1 (per patient)	Randomised using REDCap
Follow up clinical assessment	1 (per participant)	Completed a participant follow up at 1 week, 6 week or 3-month time point
Training a colleague on FLARE trial research procedures	1 (per colleague trained)	Training certificates and delegation log entry for colleague trained. Collaborator to make YTU team aware of cascading the training
Total points required	**10**	***10 points can be collected in any combination of the above activities***

You must also agree to the following;
1. It is your responsibility to present evidence to YTU when you accumulate 10 points (or more).
2. You are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
3. You are responsible for ensuring YTU have your current contact details.

If collaborator status is achieved, YTU will issue you with a certificate.

Reference: 1. https://authors.bmj.com/policies/bmj-policy-on-authorship/

Principal Investigators (PIs)

PIs are responsible for conduct of the trial at site, ensuring that;

- the dignity, rights, safety, and wellbeing of participants are given priority at all times
- each member of the research team is suitably qualified by education, training, and experience
- procedures are in place to ensure collection of high quality, accurate data
- Serious Adverse Events (SAEs) are reported in a timely and accurate manner

For PIs to be recognised as cited collaborators, they need to fulfil the following:

Site trial team

- Overall leadership and engagement of the trial team at site
- Support of trainees and of the trial process
- Ensure trial team are trained for their delegated tasks
- Keep the delegation log up to date

Trial processes

- Ensure completion of follow up
- Meet the recruitment target specified in the site agreement
- Ensure screening data is maintained
- Report and review safety events in a timely manner

Other

- Promotion and dissemination of the trial to the local department/hospital
- Timely responses to emails

If there is any concern as to whether these activities have been conducted, the central team may ask for evidence. The co-Chief Investigators will take the final decision on whether a PI will be a cited collaborator.

21. General trial information

FDP and FDS surgical intervention

The repair of FDP alone or the repair of FDP and FDS should be completed as per local current surgical training and local guidelines. Suture choice and technique will be pragmatic.

Choice of anaesthetic will also be pragmatic and based on patient and surgeon preferences, and availability. Post-operative care will be in line with routine practice at the participating site.

Re-calibration of dynamometer

Re-calibration is the responsibility of the site team to fund and complete as per the mNCA.

Re-calibration of the dynamometer is recommended on an annual basis.

Investigator Site File maintenance

Each site will have an eISF provided by YTU, consisting of all the essential documents. Delegated team members will be responsible for keeping this up to date. A list of essential and suggested contents will be provided.
All data collection will be via REDCap, and we encourage all trial documents to be maintained in electronic format. If paper documents are needed during the trial, a paper folder of key documents may be created locally and maintained as appropriate, however the location and type of such documents should be clearly indicated in a file note within the eISF (e.g., paper original consent forms if used, or original paper Patient Baseline Questionnaire completed by the participant). Furthermore, electronic and paper documentation containing identifiable information should be maintained as per FLARE protocol for confidentiality purposes.
Documentation provided by YTU must be filed in the appropriate folder in the ISF. If this document replaces an old version, move the old version to the superseded section.

Associate Principal Investigator (API) scheme

The FLARE Trial is registered with the NIHR Associate Principal Investigator Scheme which enables a Speciality Trainee or other health professional to gain experience in trial procedures whilst gaining recognition for their contribution. The PI can delegate duties to the API; however, the overall responsibility remains with the PI and guidance should be provided. For more details, please refer to the Associate PI Manual.
Links to further information on the NIHR website are as follows:

- API scheme FAQs: https://www.nihr.ac.uk/documents/associate-pi-scheme-faqs/11698
- NIHR API scheme: https://www.nihr.ac.uk/health-and-care-professionals/career-development/associate-principal-investigator-scheme.htm
- NIHR surgical research: https://www.nihr.ac.uk/explore-nihr/specialties/surgery.htm

To participant in the API scheme, please click on this link: https://www.nihr.ac.uk/career-development/clinical-research-courses-and-support/associate-principal-investigator-scheme/apply, followed by 'Apply to become an Associate PI trainee on NIHR Learn'.

Monitoring

Remote monitoring is completed once a year. YTU will send remote monitoring checklists for sites to complete and return. On-site monitoring will not occur unless triggered by issues identified at site.

Qualitative study

As part of the FLARE Trial, we are planning to conduct qualitative interviews with 10 surgeons and 10 hand therapists who have been involved in running the study. The interviews will focus on your experience of delivering the intervention, challenges/facilitators associated with delivery of trial interventions, recruitment optimisation, and what information/training would be required in order to implement the findings from the trial across the NHS. The interviews will be conducted using either telephone, videoconferencing (e.g., Microsoft Teams or Zoom) or face-to-face, according to respondent preferences and practicalities.

Should you wish to obtain more information about being involved, please contact Ann Hewison on ann.hewison@york.ac.uk.

Please note that the YTU qualitative researcher is responsible for contacting, consenting and interviewing the patients as part of this trial, rather than the site team.

Site payment

Site payments are processed on a 6 monthly cycle.
Partial payments will be made depending on the participant's whereabouts in the trial when the payment cycle has started.
A breakdown of the per patient fee, along with further information, is available within the mNCA.
Please note that a participant is defined as 'any person who consents and is enrolled (randomised) to take part in the Study'.

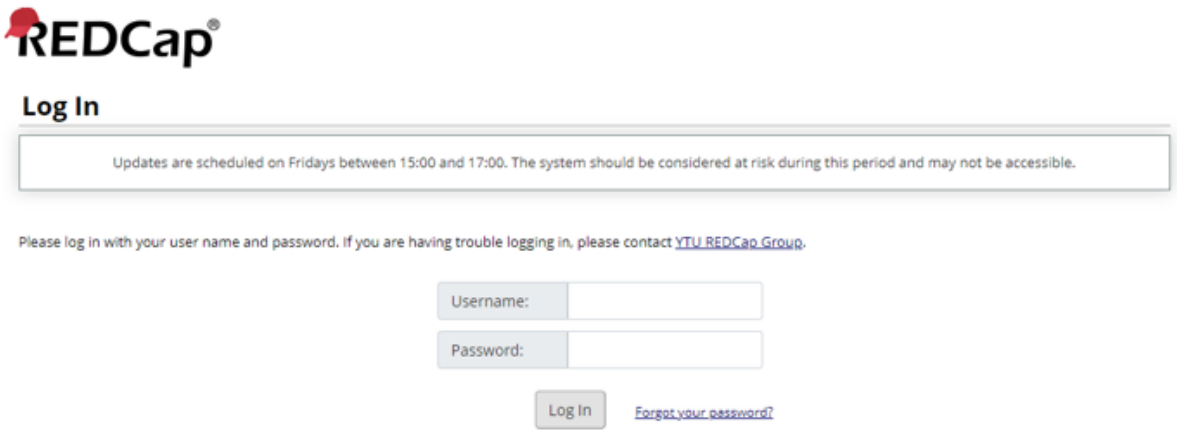
22. REDCap database

Please be aware that the REDCap database uses logic to determine which questions should appear based on previous responses, and therefore the content of instruments on REDCap may appear differently for participants.

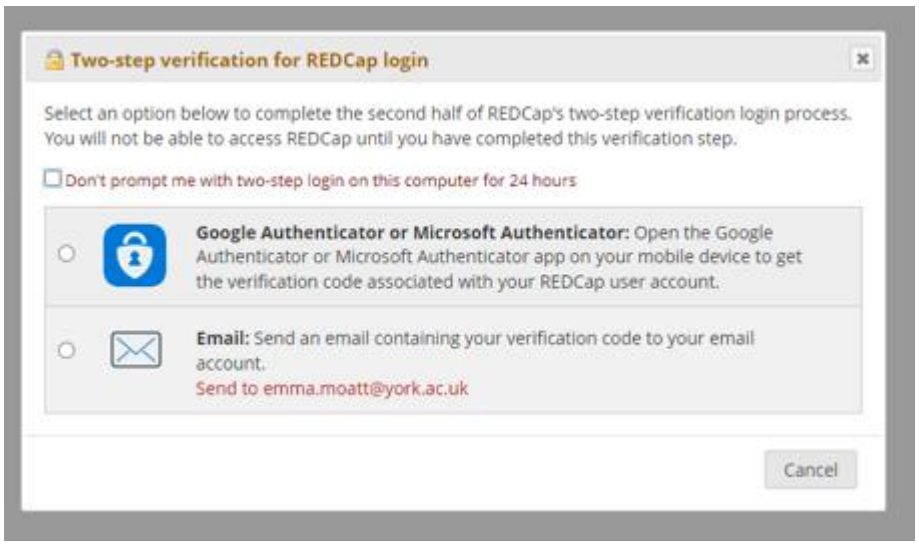
Logging onto REDCap

- Go to **https://redcap.york.ac.uk/** and complete your username and password. Complete the two-step verification process using email, Google authenticator or Microsoft authenticator. Please note that we recommend using the authenticator apps rather than email.

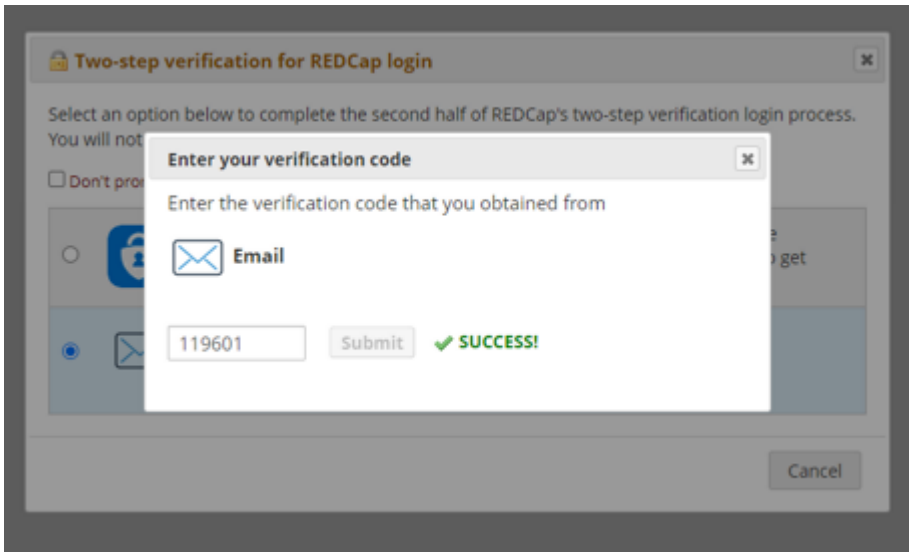
- You will receive instructions for setting up the 2-factor authentication via email the first time you are registered with the REDCap system.



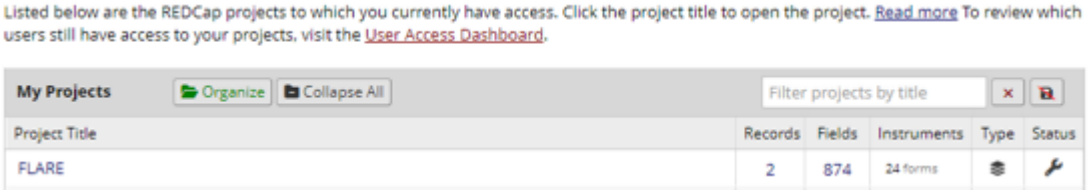
- The following popup will appear, select the option you want to use to authenticate.



- Enter the verification code.



- Click on FLARE under 'My Projects'.



Please note that, once you have completed the above set up tasks, we would recommend that you also set up Google or Microsoft Authenticator (guidance available in the section below).

How to setup the Google Authenticator or Microsoft Authenticator for the 2-factor authentication required for REDCap:

- Install the Google Authenticator or Microsoft Authenticator app on your mobile device
- Login to REDCap (https://redcap.york.ac.uk/) and click 'Profile' (on the right-hand side of the screen)
- Under 'Login-related options:' click 'Set up Google Authenticator or Microsoft Authenticator for two-step login'
- Follow the on screen steps to link the app to REDCap

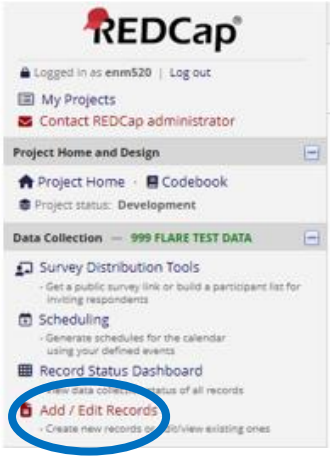
If the authenticator is asking you to scan a QR code which takes you back to the home page, please log into your REDCap account via email instead. Once logged in click on 'profile' and under 'log-in related options' click on 'set up Google Authenticator or Microsoft Authenticator for two-step login'. A new window will then open. Please follow these instructions.

If you already have the Google Authenticator app installed, please do the following:

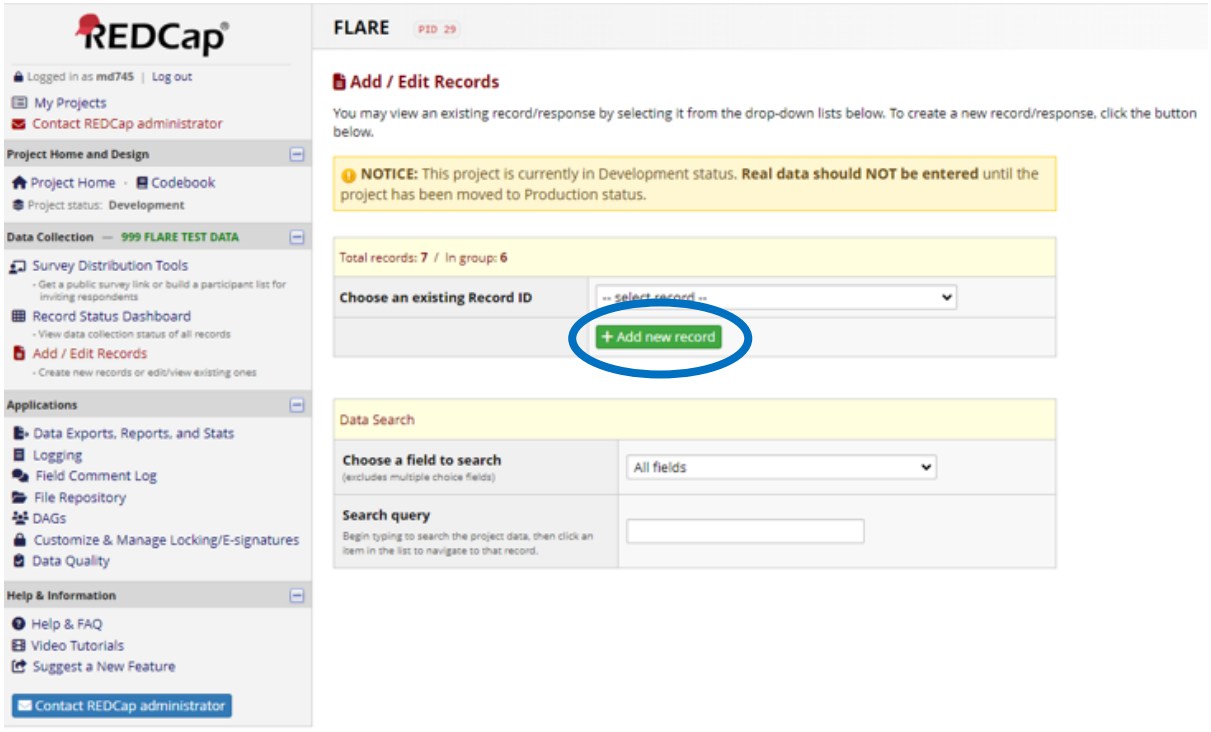
- Open the Google Authenticator app and click on the '+' sign in the bottom right-hand corner
- If asked, select the account type 'other'
- Select 'Scan a QR code'
- Login to REDCap (https://redcap.york.ac.uk/) and click 'Profile' (on the right-hand side of the screen)
- Under 'Login-related options:' click 'Set up Google Authenticator or Microsoft Authenticator for two-step login'
- Scan the QR code and follow the on screen steps to link the app to REDCap

Creating a patient record on REDCap

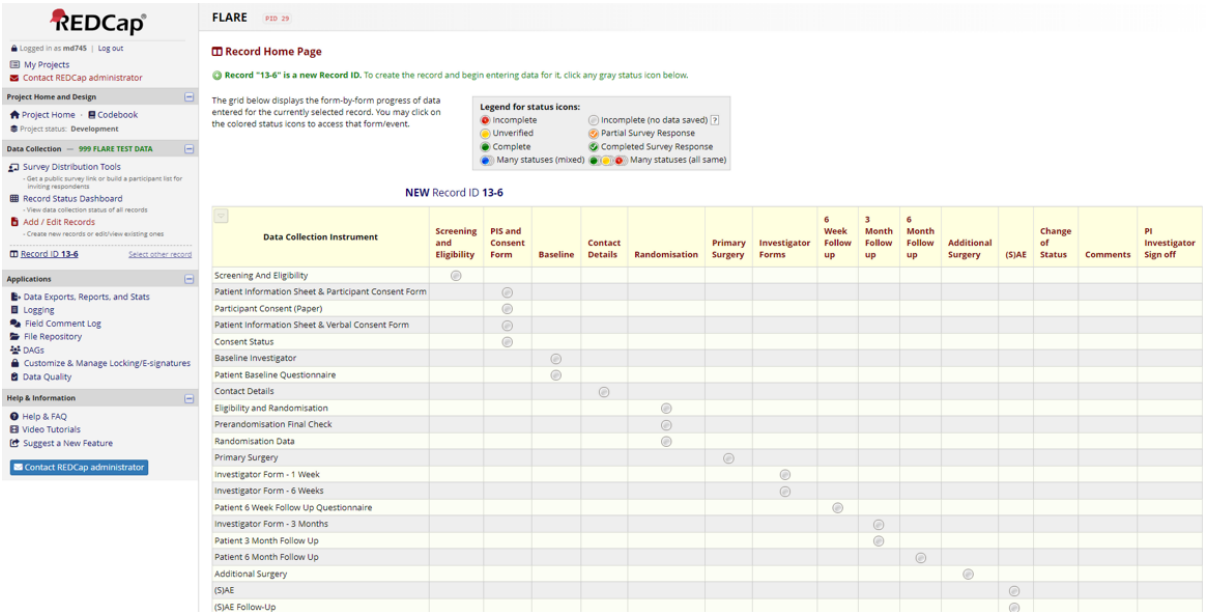
1. Click on 'Add/Edit Records'.



2. Click on '+ Add new record'.

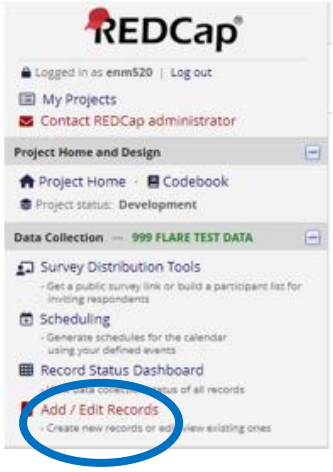


3. REDCap will confirm a new record has been created and show all instruments available for the patient.

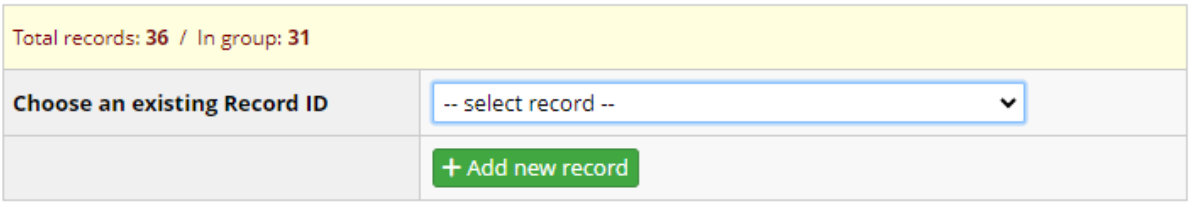


Searching for a participant record

- Click 'Add/Edit Records'.



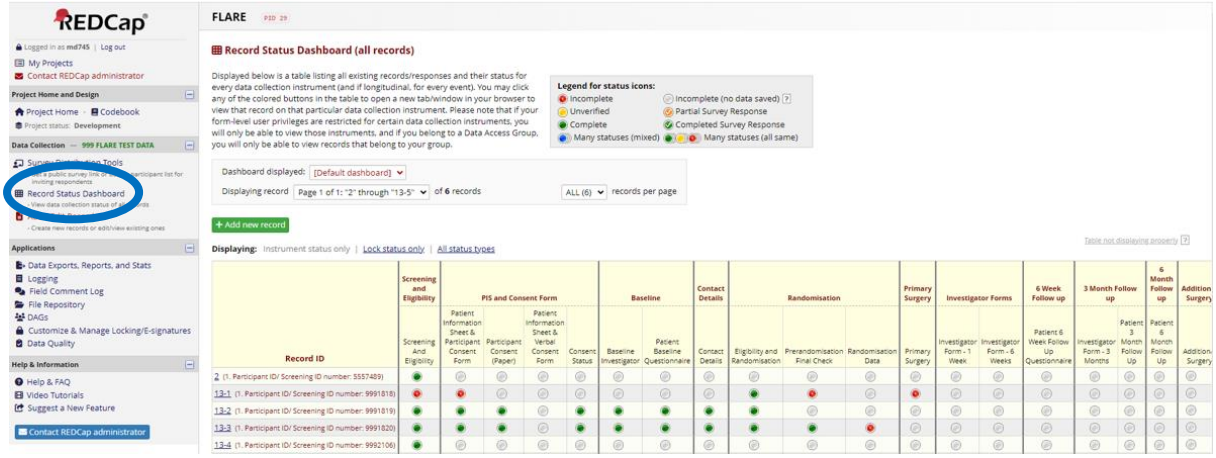
- Under 'Choose an existing Record ID', select the participant's ID number.



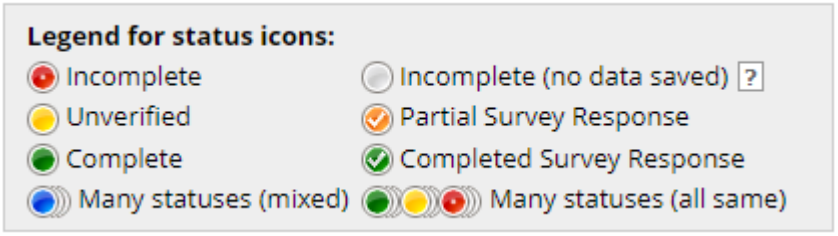
- The participant's Record Home Page will then load

Viewing 'Records' on REDCap

• Select 'Record Status Dashboard'. This will show a table of all participants added to REDCap at your site and the status of all the trial forms to be completed; these are referred to as 'instruments'.



Coloured dots and ticks indicate the status of instruments, as shown below;

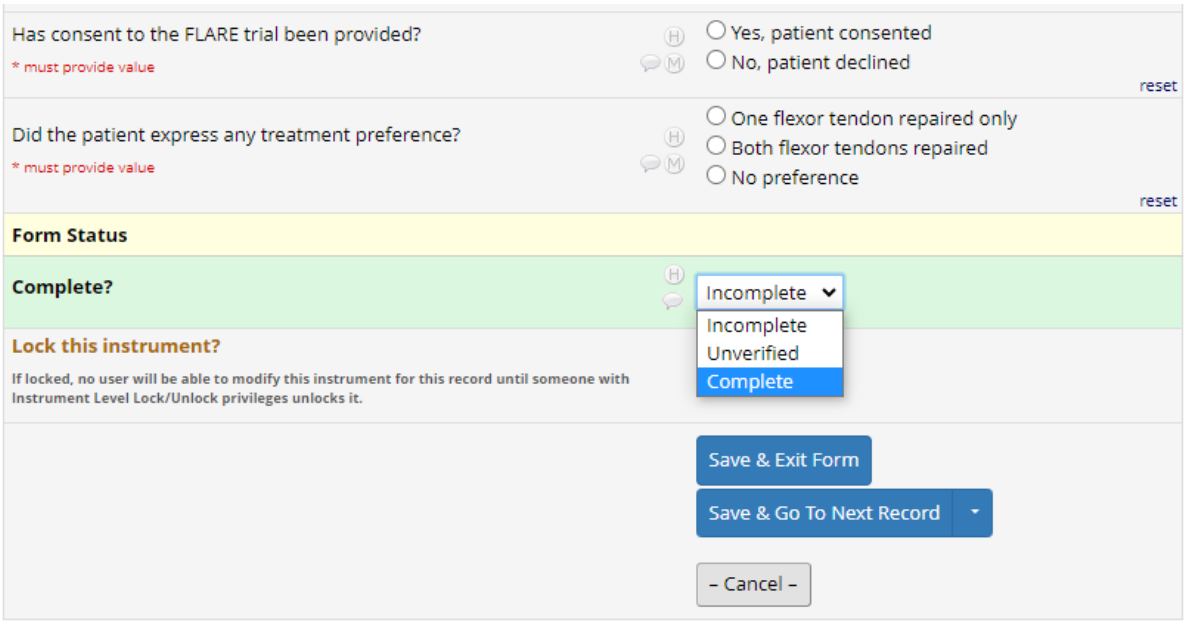


Instruments can be edited or viewed by clicking on the corresponding dot.

Completing instruments on REDCap

Please complete as much information as possible on the REDCap instrument and check for any missing data prior to saving.

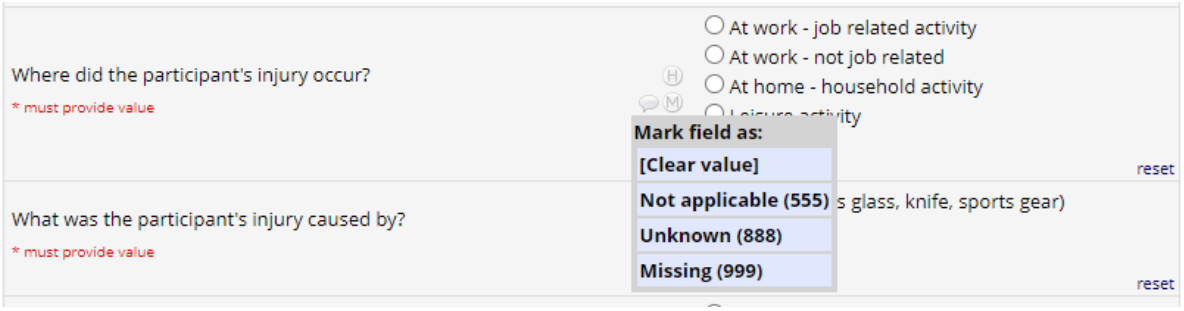
If you have checked and there is no missing data, please ensure that the Form Status is recorded as 'Complete', and this has been saved.



Please note, data can be inputted and saved onto REDCap without an internet connection. However, an internet connection is required to complete randomisation on REDCap.

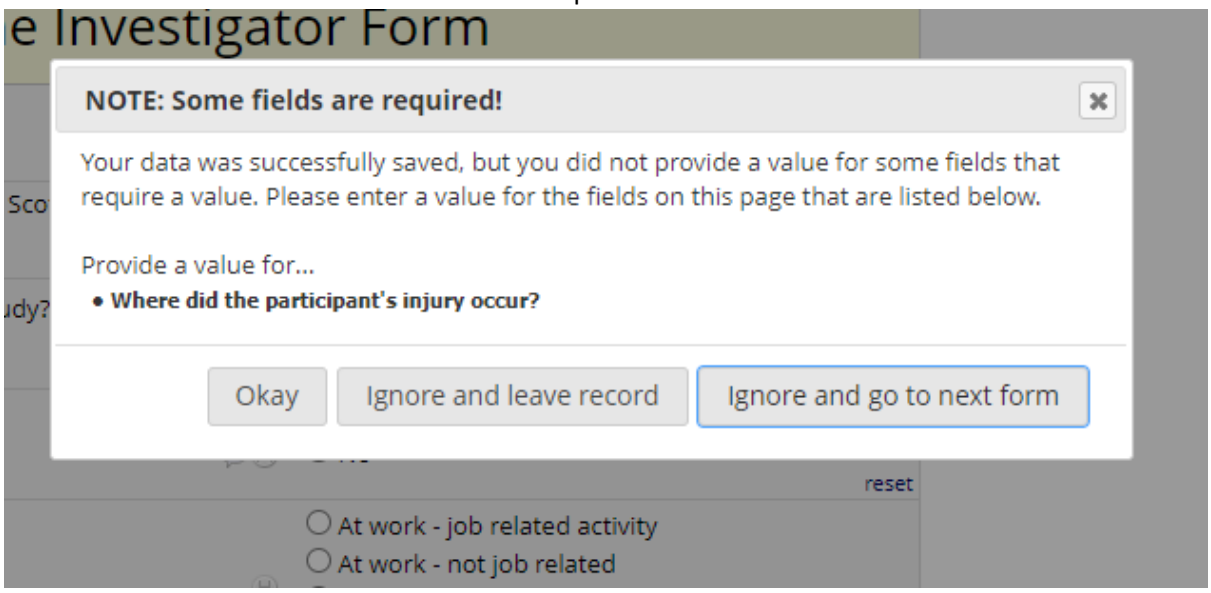
Missing fields

All fields that are required to be completed have the red '*must provide value'. If this data is not applicable, unknown, or missing, you can indicate this by selecting the 'M' circle (shown below) to open up the dropdown list and select the appropriate option.



Saving instruments with incomplete data

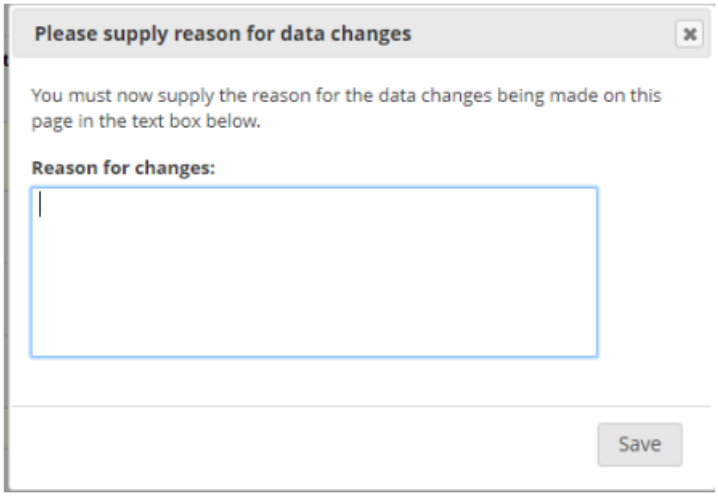
If you need to leave an instrument before all sections are complete, scroll to the bottom and select 'Save and Exit Form'. You will receive a pop-up message advising that not all data fields are complete. Where possible, please complete the required fields. If you would like to save this instrument to complete later, select 'Ignore and leave record' or 'Ignore and go to next form'. The dashboard will now show a red circle for 'incomplete'.



Making changes

You can make changes to any saved instrument that has not been locked by YTU. Open the instrument, make the necessary changes, and click 'Save and Exit Form'. If an instrument has been locked by YTU, a padlock will be displayed below the colour status circle. Please email the YTU team to request that the instrument is unlocked.

A text box will appear asking the 'Reason for changes', as shown below:



Enter the reason and save. We encourage use of the following shortcuts:

1	**1**st time data entered for this field
T	Data entry error or **T**ypo
N	**N**ew information available
O	**O**ther

Repeatable instruments

Some instruments are repeatable and indicate instruments that may be required to be completed more than once e.g., to report an Adverse Event. Please ensure that the following instruments only contain details relating to one instance (e.g., one additional surgery, one adverse event). Extra instruments can be added for the following:

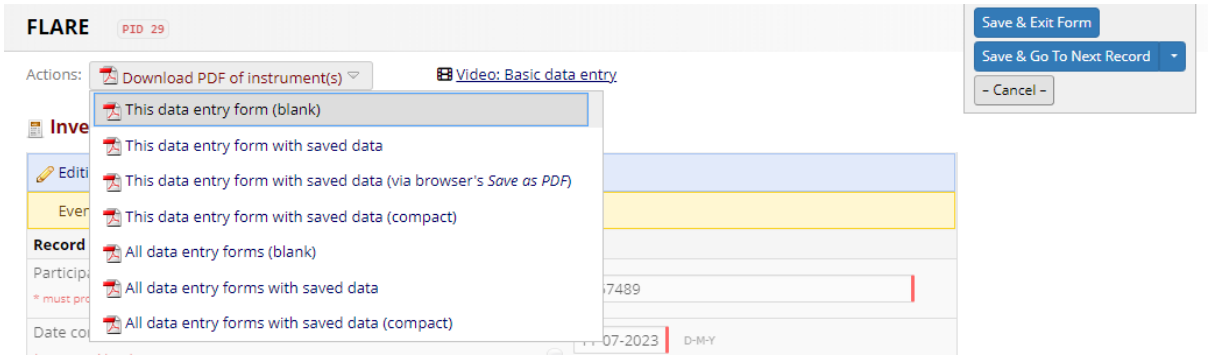
- Comments
- Additional surgery
- Change of Status
- (S)AE
- (S)AE Follow-up

• If this is the first time the instrument will be completed, there will be a transparent circle to select (on the Record Dashboard, as per usual).
• If this is the second (or later subsequent) time the instrument will be completed for this participant, there will be a green circle (representing the first completed instrument) with a plus sign to one side (as shown below). Select the plus sign to open a second instrument.

• Details of the previous instruments completed are displayed in the summary table for 'repeating instruments' (found by going into the participant's record). Please use this summary to check that data is not being repeated and to ensure all relevant data is recorded.
• Selecting '+ Add New' from the relevant table will open a new repeatable instrument.

Printing REDCap instruments for completion on paper

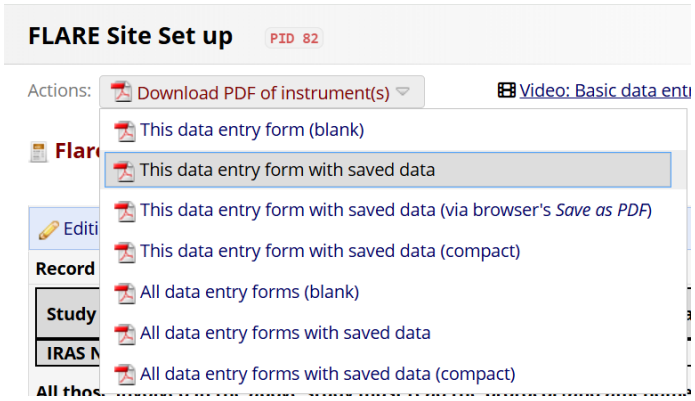
Should the team member conducting a visit not have easy access to REDCap, the Investigator Form instrument can be printed from REDCap by selecting 'Download PDF of instrument(s)' and selecting 'This data entry form (blank)', as shown below. The data can then be captured on paper and entered onto REDCap by a delegated member of the team. Site staff will then need to carefully enter the data on REDCap, check the responses on REDCap match those on paper, and ensure the information is saved and the instrument is marked as completed. Please file the paper copy of the instrument in the ISF.



Printing REDCap instruments with saved data as a PDF

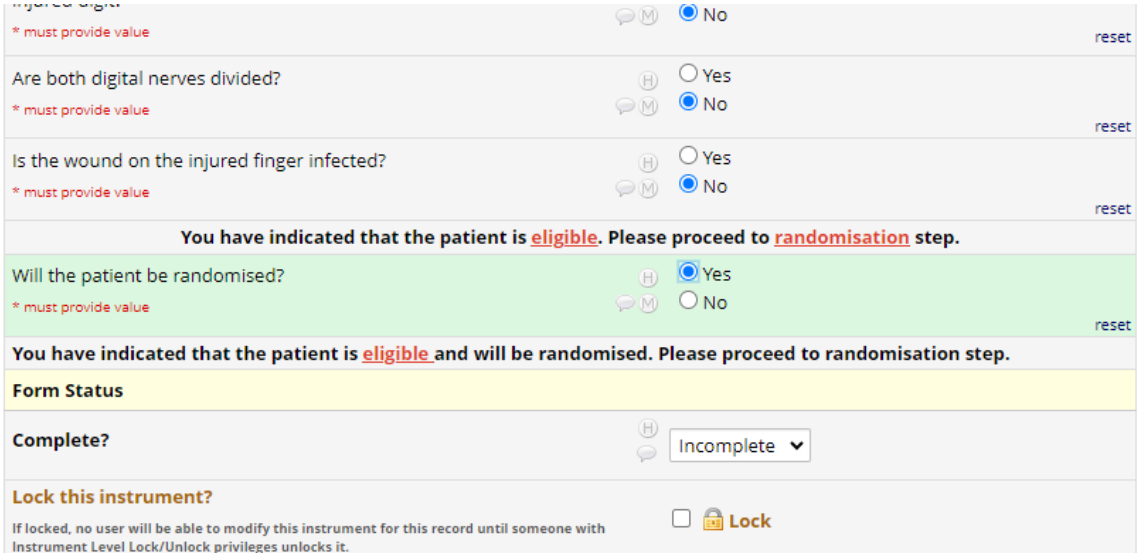
If you need to download a REDCap instrument as a PDF containing the saved data, either for filing the completed delegation log entries or for unblinding the patient's medical records, please complete the following steps:

1. Open the instrument that you would like to download
2. Select 'Download PDF of instruments' at the top of the screen (see image below)
3. Click on 'This data entry form with saved data'

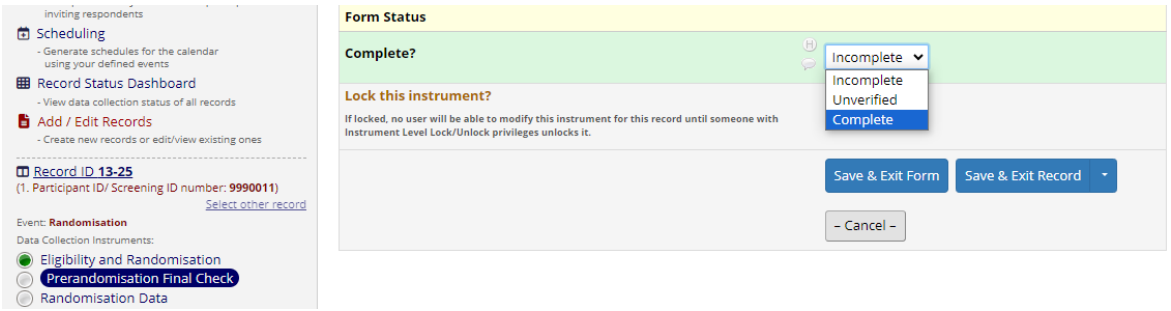


How to randomise on REDCap

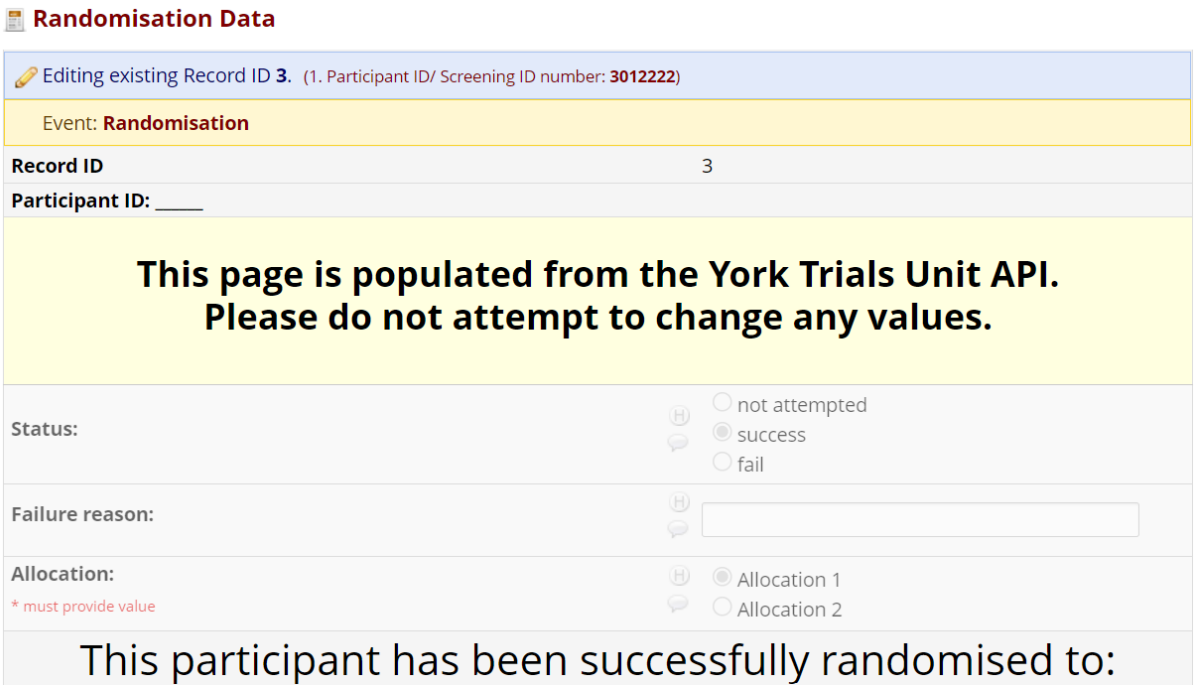
- Find the patient's record on REDCap; please ensure that you are using the correct record
- Complete the *Eligibility and Randomisation instrument* on REDCap, ensuring you select 'Yes' in response to the question "Will the patient be randomised?"
- Mark the Form Status as 'Complete'



- Open the *Prerandomisation Final Check instrument* on REDCap, change the Form Status to 'Complete', and click 'Save and Exit Form'. No data entry is required on this page.



- Open the *Randomisation Data instrument* on REDCap to view the randomised treatment allocation


Randomisation Data
Editing existing Record ID 3. (1. Participant ID/ Screening ID number: 3012222)
Event: Randomisation
Record ID 3
Participant ID: _____
This page is populated from the York Trials Unit API.
Please do not attempt to change any values.
Status:
not attempted
success
fail
Failure reason:
Allocation:
* must provide value
Allocation 1
Allocation 2
This participant has been successfully randomised to: