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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Sponsor: South Tees Hospitals NHS Foundation Trust

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

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

Follow us on X: @FLARE_ _Trial

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

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 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. Familiarise yourself with the key trial documents (such as the protocol, trial site manual, SIV slides, patient information sheet, informed consent form).
2. 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.
3. Complete the SST modules required.
4. Upon completion of the SST modules and reading the trial documentation, 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 you for completion.
5. Your SST certificate will be emailed to the email address documented within the Training Record Form. Please file a copy of your certificate within the FLARE eISF.

** A Study Specific Training certificate can be requested either when all necessary training has been completed, or if preferred, after each training element (if training activities are completed at separate times).*

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.

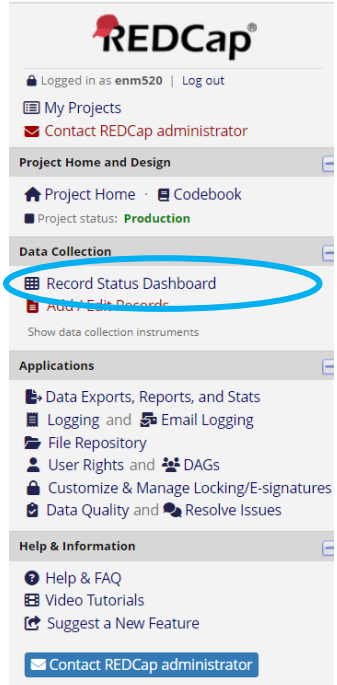
To access the NIHR Research CV template, go to https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv/ or please click here. Please ensure that you have signed and dated the CV.

Delegation of tasks

The FLARE delegation log needs to be completed by everyone who is being delegated to complete FLARE trial tasks. 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

1. 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 site name. **If you have previously worked on a YTU trial before that required REDCap access,** please include your YTU REDCap username.
2. Discuss tasks you will be delegated to complete with the PI.
3. The YTU team will process your REDCap access; please check your inbox/spam/junk folders for an email notification from REDCap regarding your access.
3. Once you have access to the FLARE delegation log on REDCap, click on 'FLARE Site Set Up' under 'My Projects'
4. Click on 'Record Status Dashboard'



5. 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'

6. 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'
7. Click on the dot next to 'FLARE Site Delegation Log', complete the form based upon your delegated tasks, keep the 'Form Status' as 'Incomplete' and click 'Save & Exit Form'
8. Once the PI has signed your delegation log entry, change the 'Form Status' to 'Complete' and click 'Save & Exit Form'
9. Once this has been completed, the YTU team will review your delegation log entry against your FLARE Trial Training Record Form.
10. If there are no queries, and your site is open to recruitment, access to the FLARE REDCap database will be granted.

If you are the Principal Investigator, please complete the steps specified above, along with completing the 'Delegation Log- PI Responsibilities' instrument, change the form status to 'Complete', and click 'Save & Exit form'.

Delegation log key points

- Please check that the delegation log is fully completed before asking the PI to sign off your entry.
- **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 the PI has signed off your delegation log entry and a change to the delegated tasks is made,** the delegate and PI are required to re-sign the delegation log entry and update the date of signature section.
- **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.
- **If existing members leave the team**, a task end date should be entered onto their delegation log entry in REDCap and the YTU team need to be notified.
- **Please use your own REDCap account to complete the FLARE delegation log.** Do not complete the delegation log through another user's REDCap account.
- **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 delegated clinician present at surgery to confirm eligibility 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.

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 team and research team	Trial Overview
B. Confirmation of trial eligibility	Surgeons only	Trial Overview
C. Obtain informed consent (explain study risks and objectives)	Surgical team and research team	- Trial Overview - Consent
D. Clinical evaluations (including Range of Motion)	Research team, hand therapists	- 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	Surgical team	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.

Surgeon trial training/delegation log entry

A surgeon completing **only the surgical repair** does not require specific FLARE Trial training or entry onto the delegation log. However, there does need to be a trained and delegated individual who can complete the eligibility assessment at surgery and randomisation.

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

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 20 (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

How to randomise on REDCap

4. Screening and eligibility

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 participant ID is entered correctly as it cannot be amended in the REDCap system.**

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, and 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.**
Please note that all patients who are 16 years old or over with findings suggestive of flexor tendon injury on clinical assessment (straight finger with a cut and inability to bend) should be assessed against the screening eligibility criteria.

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	The thumb flexor tendon anatomy differs from that of the digits and cannot be directly compared. Single digit allows for accurate assessment of outcome for that digit without the confounding effect form an additional digital injury
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
Injuries affecting multiple zones	The outcome from repair of a flexor tendon which has been 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 form 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 injury to 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

<u>Ineligible patients</u>

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.

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)

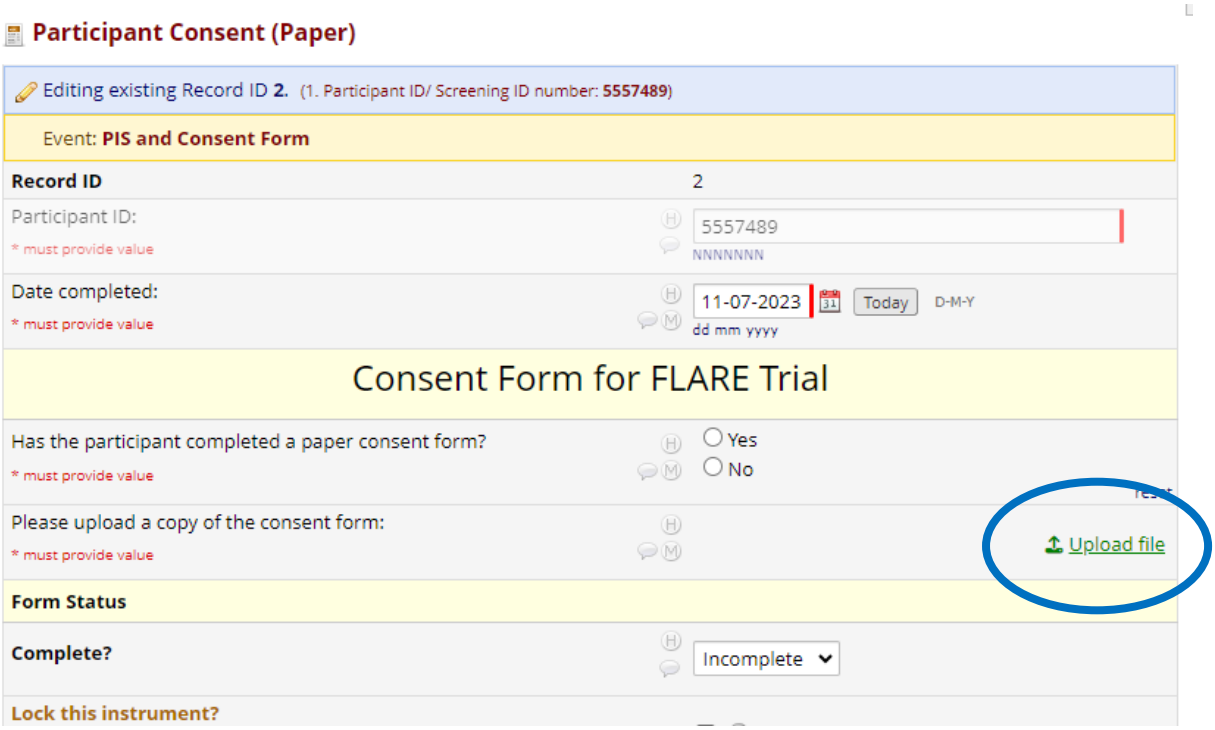
The site team need to assure themselves that the patient is fully informed before completing consent. If patients lack capacity to consent, they are not eligible to participate in FLARE.

<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 20 (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 20 (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'



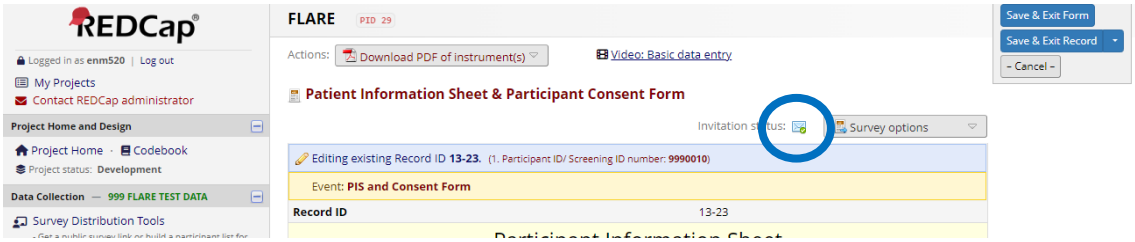
Obtaining informed consent remotely via email

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.

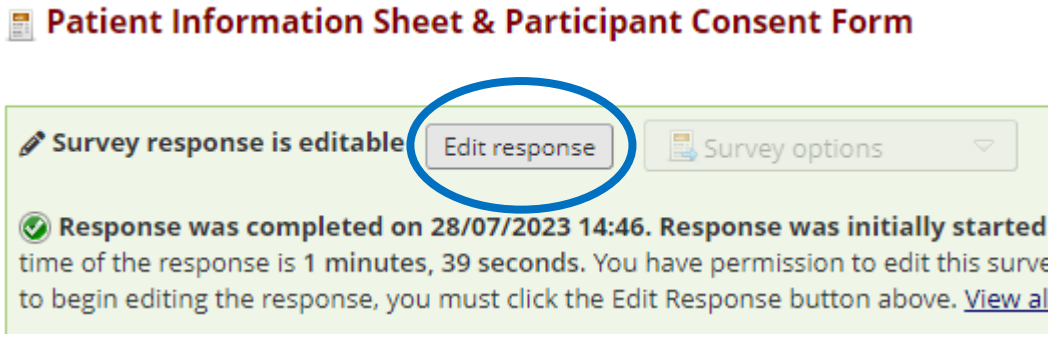
1. Ensure the patient has had the opportunity to read the PIS and ask any questions they may have
2. Find the participant's REDCap record; guidance on how to complete this can be found in section 20 (REDCap database)
3. Once you are on the participant's Record Home Page, select the dot on the 'Patient 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. 1 copy given to the patient by the site team (cannot be automated via REDCap)
2. 1 copy filed or uploaded into the patient's medical notes
3. 1 copy filed or saved in the Investigator Site File/generate file note to state that the consent form is stored in the 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. 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 20 (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.

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 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 *Patient Baseline Questionnaire* in the ISF.

7. Eligibility assessment at surgery and randomisation

Eligibility assessment at surgery

At surgery, a delegated surgeon reassesses the participant's eligibility against the trial eligibility criteria. Please refer to Table 4 below;

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. 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

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

- **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.

8. 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. 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 20 where screenshots of this process are available.

9. Blinding procedure

Table 5 clarifies which individuals are blinded to the treatment allocation, 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 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 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.

Communicating blinding statements in clinical documentation/notes

In order to maintain patient and staff blinding, no technical information about the repair performed should be recorded anywhere other than in the *Primary Surgery instrument* on REDCap.

Completing the operation note / referral to hand therapy / discharge letter
Please state "flexor tendon repair performed as per FLARE Trial"

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 site 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 document this in a *Comments instrument* on REDCap, including 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

10. 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 9 (Blinding procedure))

Ineligible patients

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

11. 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 treatment allocation to the participant, blinded research site members, nor hand therapists/physiotherapists.

- 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 14 (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.

12. 6 months post-surgery

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

Site team tasks

- Upload/file a copy of the *Randomisation Data* and *Primary Surgery* REDCap instruments into the patient's medical records. YTU will contact you to advise when this can be completed.

- Review the participant's medical records to check if any Adverse Events, Serious Adverse Events or additional surgeries have occurred since the 3 month visit. If so, please record these on REDCap.

YTU tasks

- Contact the participant to complete the *Patient 6 month Follow Up Questionnaire* by email/post/phone.

- 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* REDCap 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 (expected July 2025).

13. 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.

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.

14. 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:

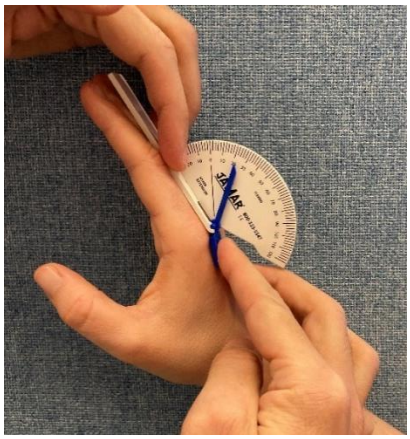
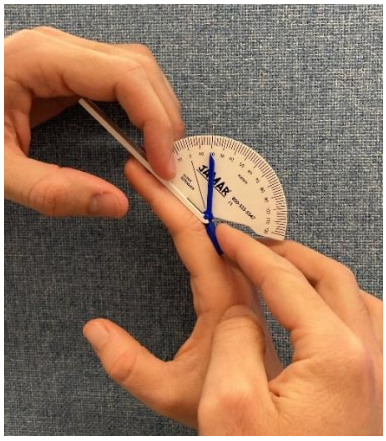
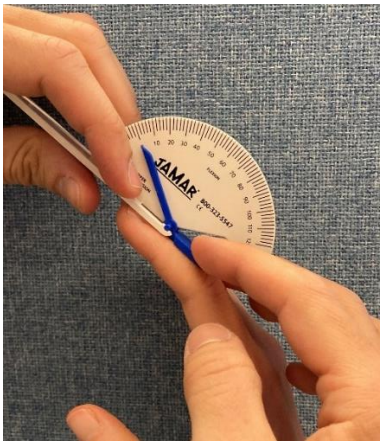
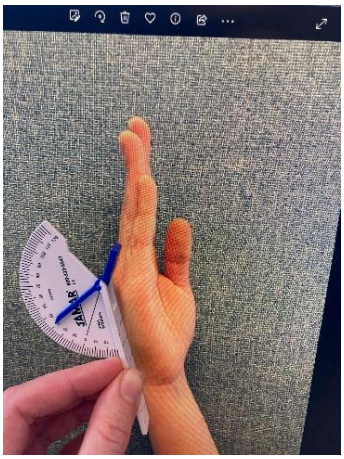
1. Check that the participant is happy for you to take the screenshot and advised that it will be deleted once data collection is completed
2. Ask the participant to hold their hand and fingers still so that a lateral view of the target finger from an ulnar or radial perspective is achieved to best visualise 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

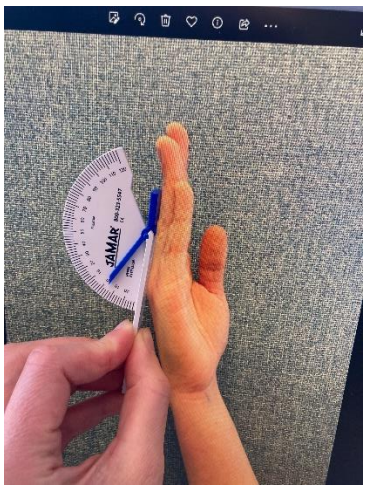
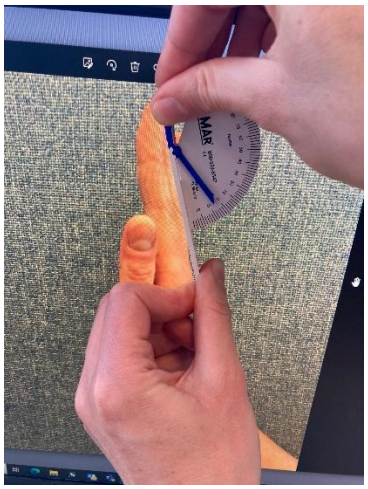
Extension ROM measurements for all joints (MCPJ, PIPJ, DIPJ)

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**

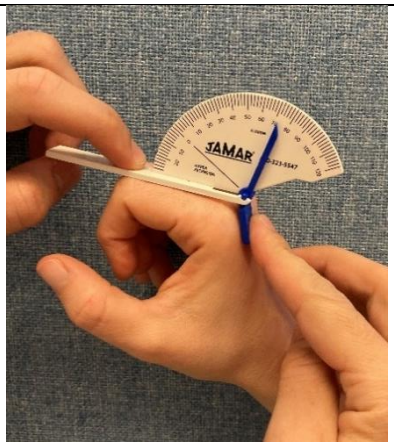
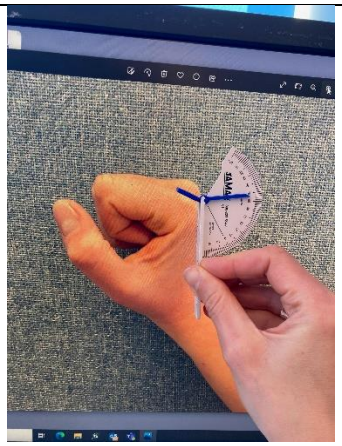
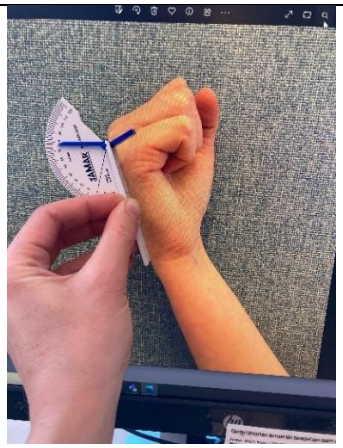

Flexion ROM measurements

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**
		

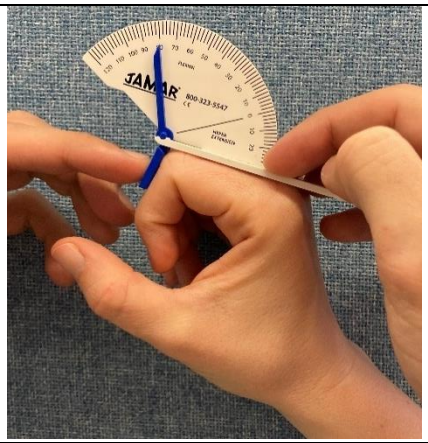
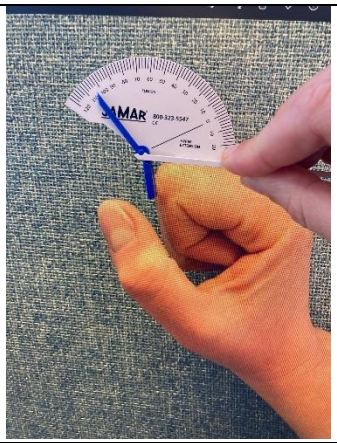
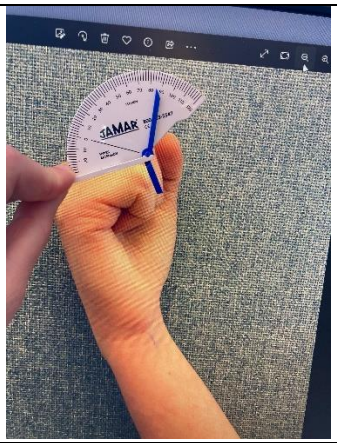
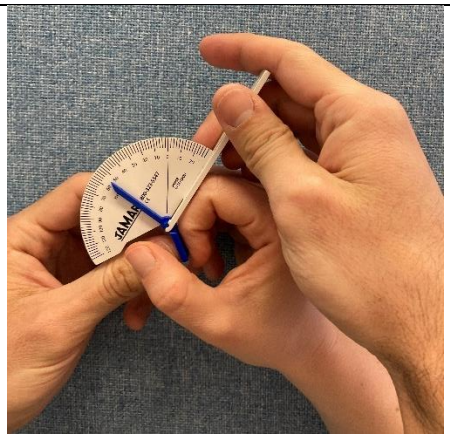
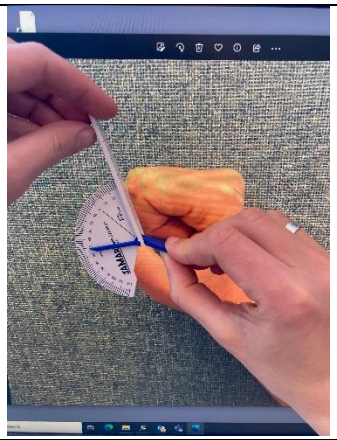
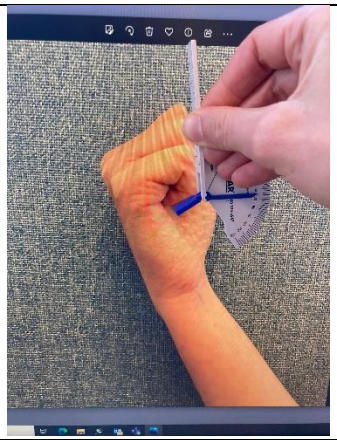
PIPJ and DIPJ

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**
		

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

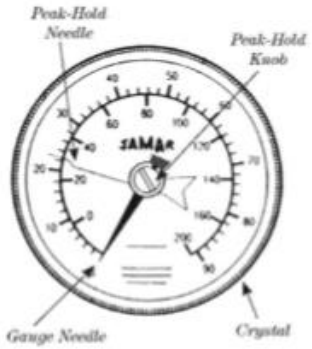


Figure 2: Dynamometer dial

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 3 Month Investigator 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.

15. 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.

Only collect **AE data** for events that are **related to the original finger injury**, **unexpected, and have occurred within six months of the participant's randomisation**.

Complications*, which might be expected with this condition and treatments, **should not be reported as an adverse event.** These **complications will be recorded in** the relevant *FLARE Investigator instruments* but do not require additional reporting.

Event confirmed as an **Adverse Event** by the PI or other delegated clinician.

Event confirmed as a **Serious Adverse Event** by the PI or other delegated clinician.

Fully complete the *(S)AE instrument on REDCap within **5 days** of becoming aware of the event.*

Fully complete the *(S)AE instrument on REDCap within **24 hours** of becoming aware of the event.*

Use the AE/SAE Tracking Log in the FLARE eISF to allocate an AE/SAE reference number.

Complete the AE/SAE Tracking Log.

Causality and expectedness, and sign-off must be confirmed on the *(S)AE instrument* in REDCap by the PI/delegated clinician

Where the AE or SAE is ongoing, an *(S)AE Follow-Up instrument* will be required **one month** after the original report. Ongoing events will be followed up until resolved/site are notified to stop by YTU. Update the AE/SAE Tracking Log as necessary.

Report all events to the host institution, in-line with local arrangements

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	

16. 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.

17. 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 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.

18.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	Completed *Screening and Eligibility instrument* on REDCap
Consent	1	Completed consent form
Randomisation/operation	1	Randomised using REDCap
Follow up clinical assessment	1	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.

19.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.

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

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 Arabella Scantlebury on arabella.scantlebury@york.ac.uk

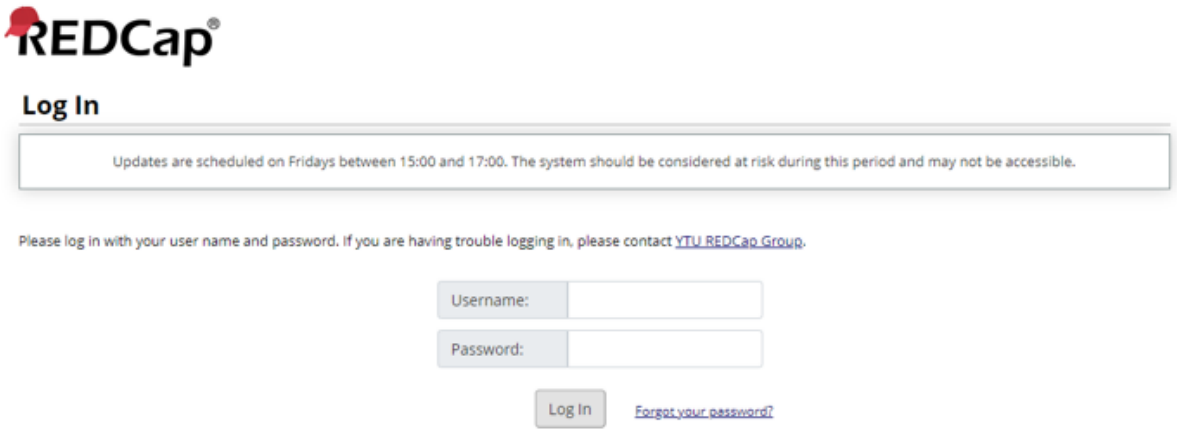
20. REDCap database

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.

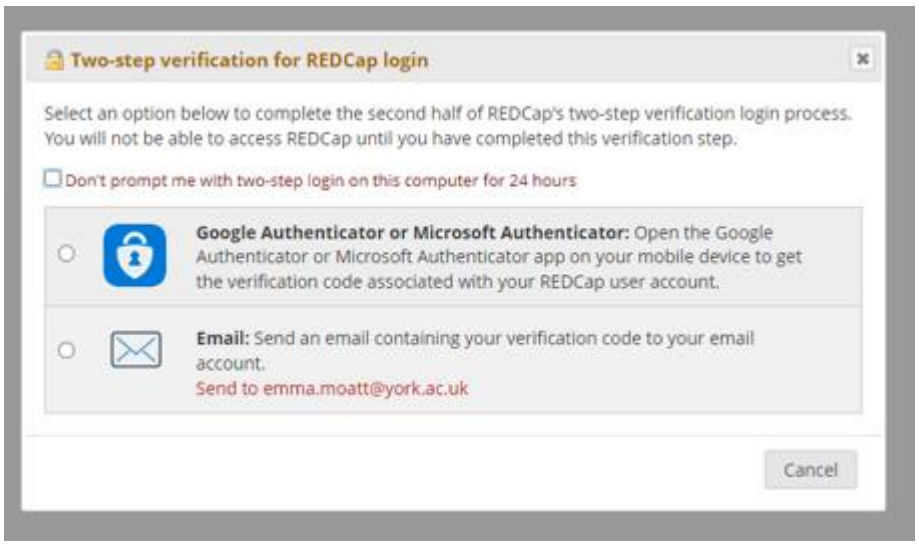
Logging onto REDCap

- 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.

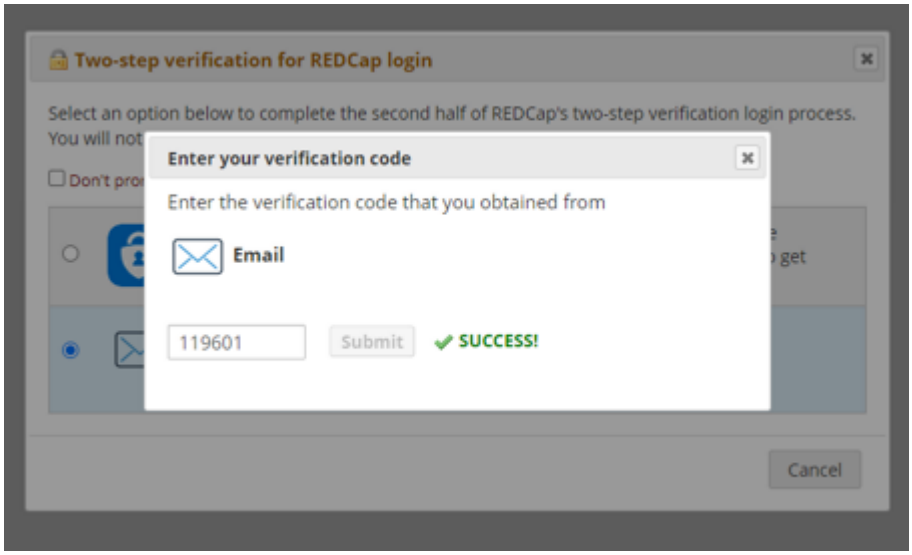
- You will receive instructions for setting up the 2-factor authentication via email the first time you are registered with the REDCap system.



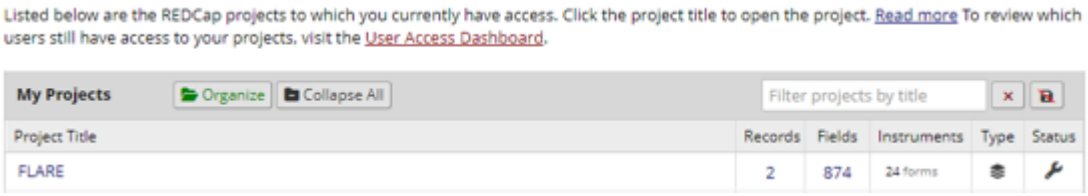
- The following popup will appear, select the option you want to use to authenticate.



- Enter the verification code.

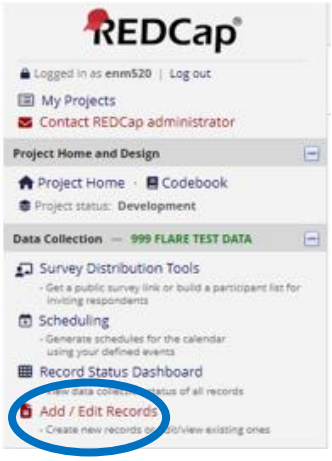


- Click on FLARE under 'My Projects'.

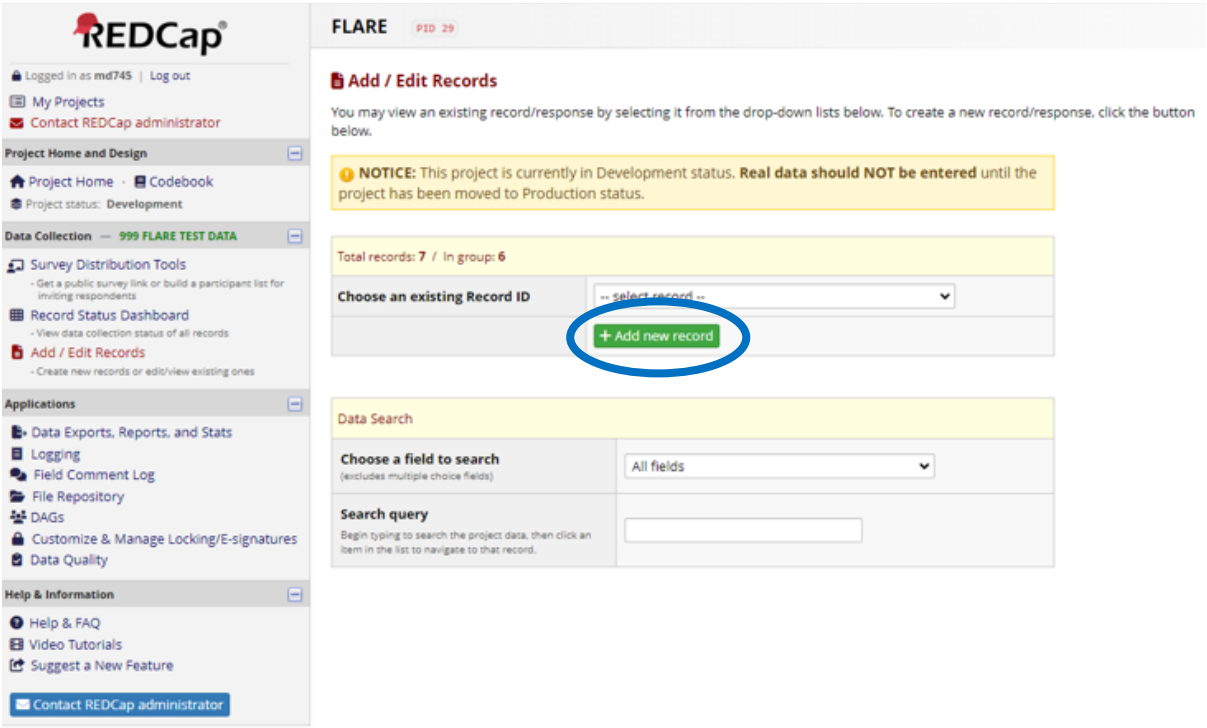


Creating a patient record on REDCap

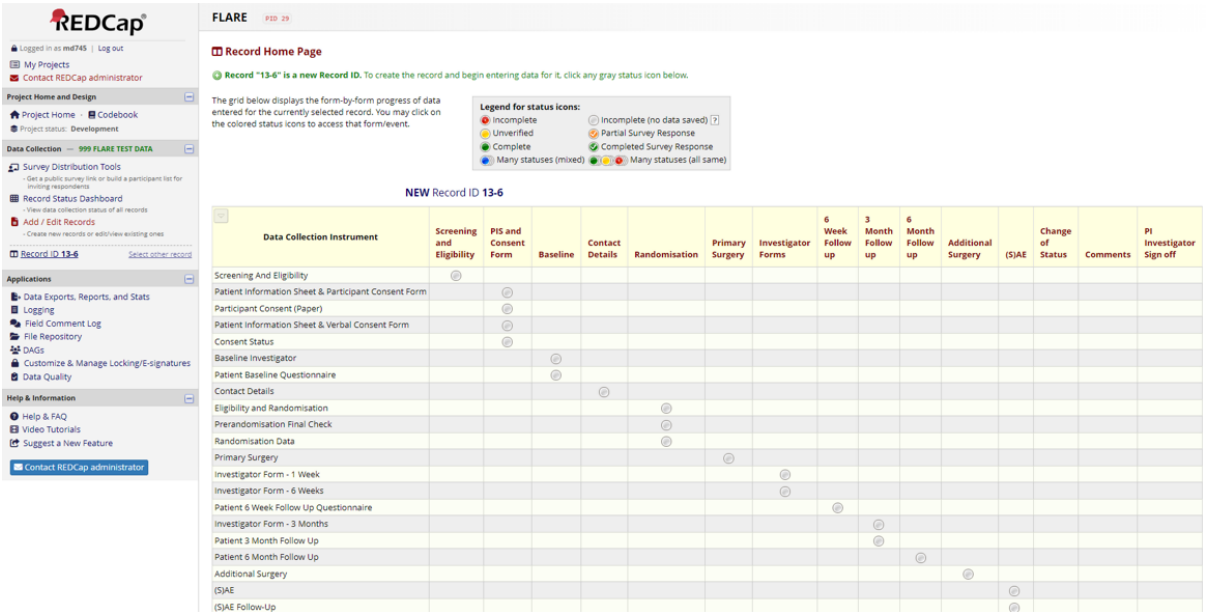
1. Click on 'Add/Edit Records'.



2. Click on '+ Add new record'.

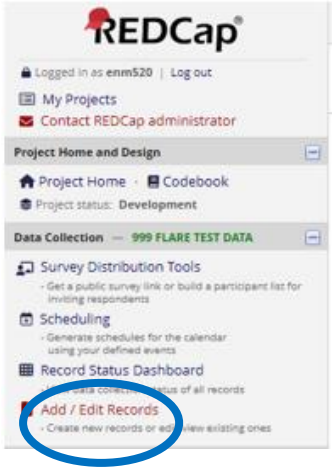


3. REDCap will confirm a new record has been created and show all instruments available for the patient.

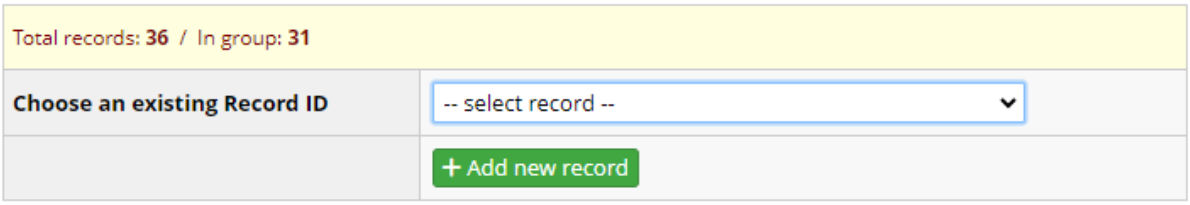


Searching for a participant record

- Click 'Add/Edit Records'.



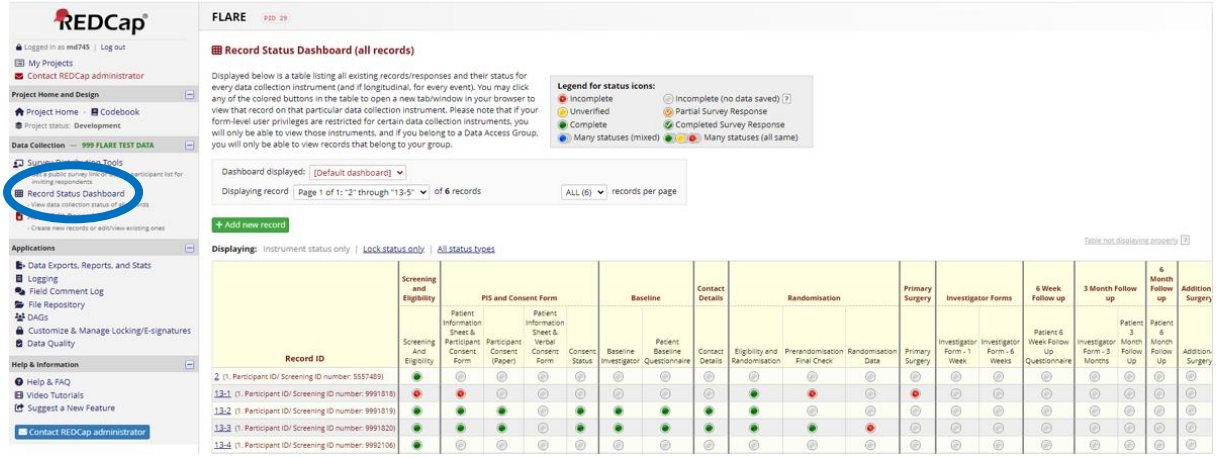
- Under 'Choose an existing Record ID', select the participant's ID number.



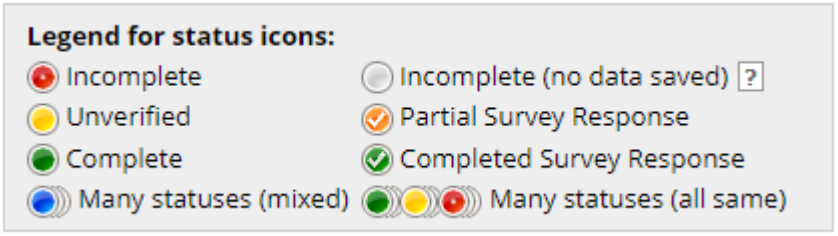
- The participant's Record Home Page will then load

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;

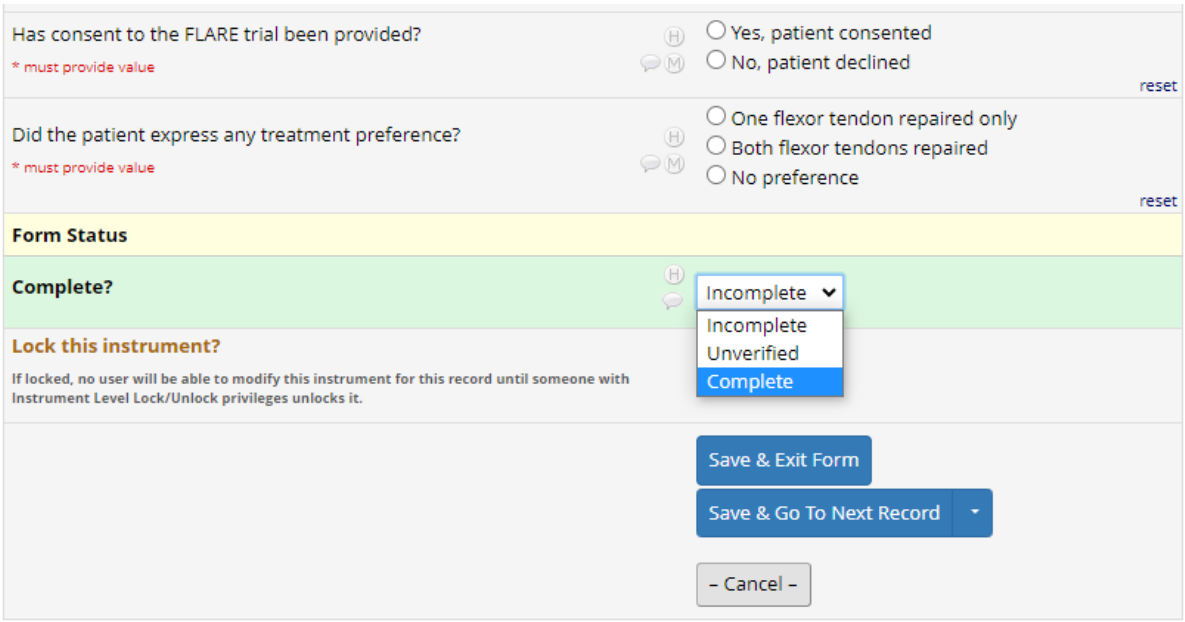


Instruments can be edited or viewed by clicking on the corresponding dot.

Completing instruments on REDCap

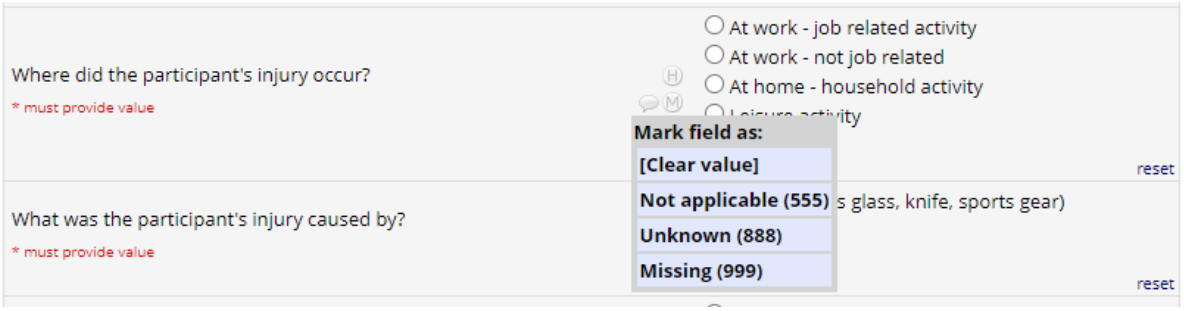
Please complete as much information as possible on the REDCap instrument and check for any missing data prior to saving.

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.



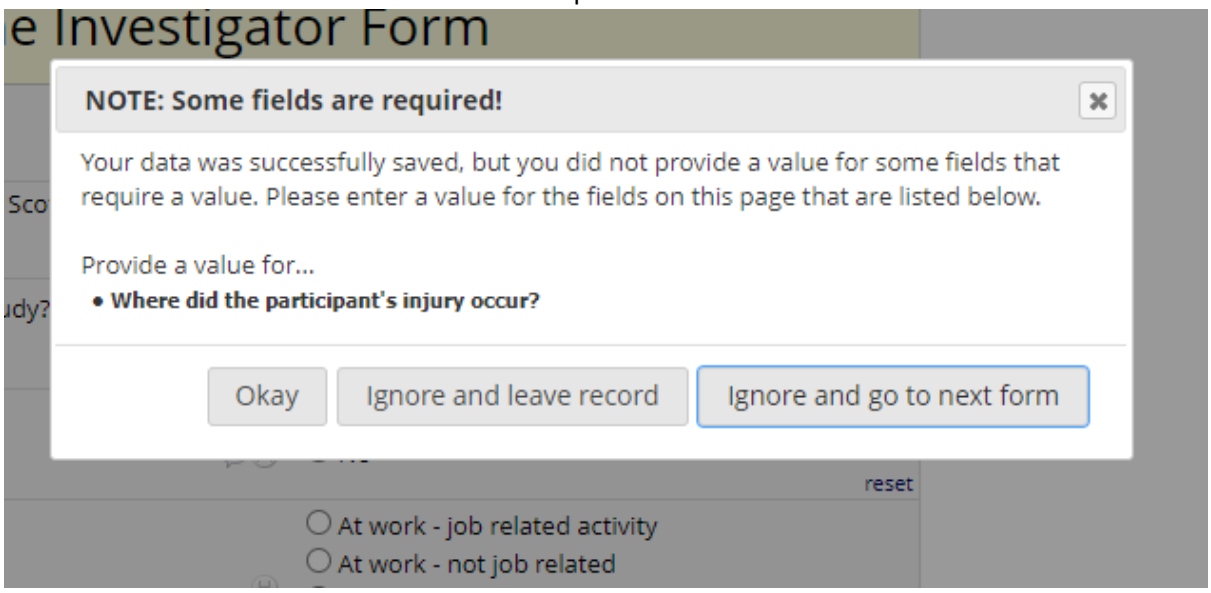
Missing fields

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

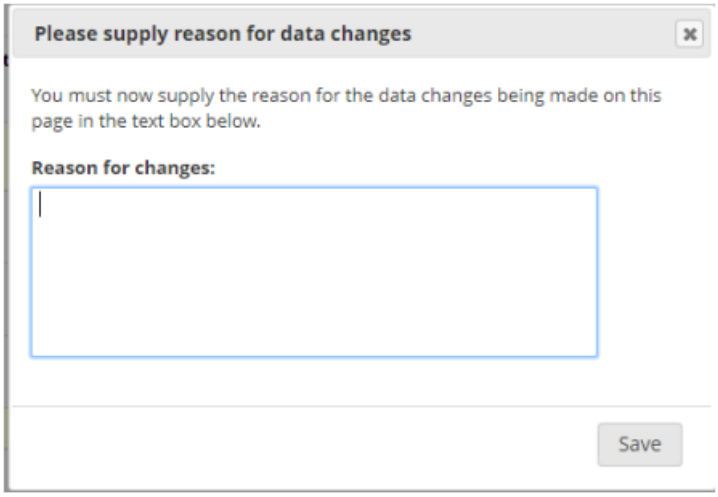
If you need to leave an instrument before all sections are complete, scroll to the bottom and select 'Save and Exit Form'. You will receive a pop-up message advising that not all data fields are complete. Where possible, please complete the required fields. If you would like to save this instrument to 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:

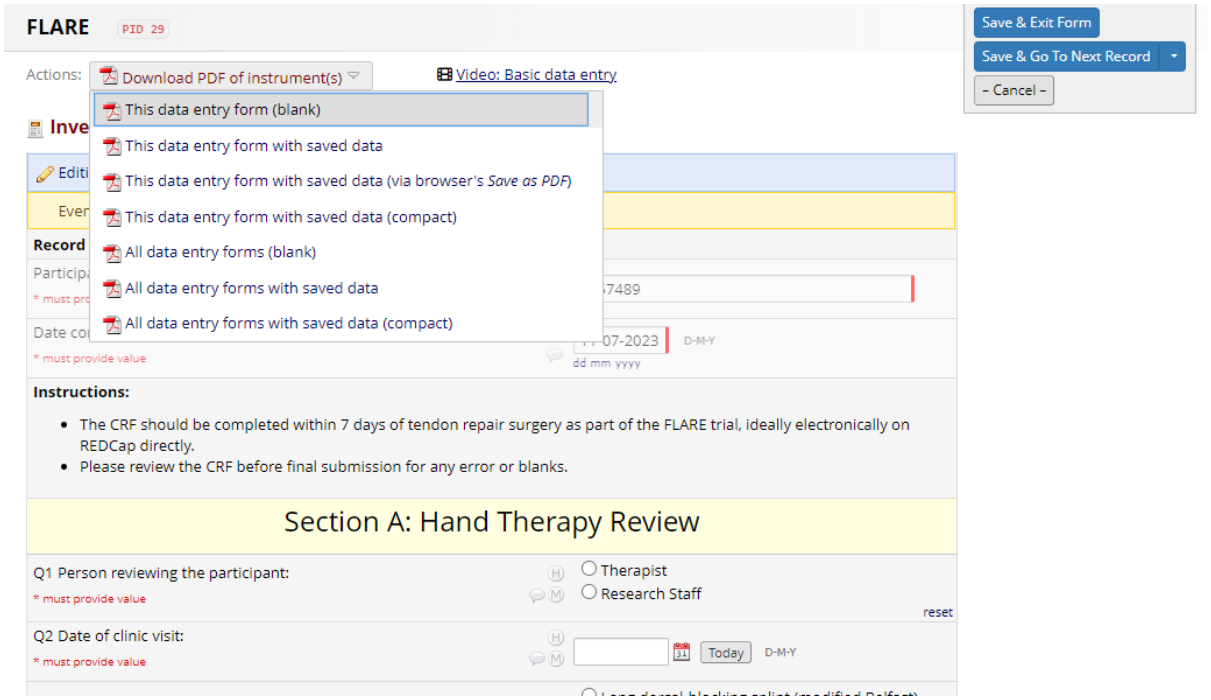
- Comments
- Additional surgery
- Change of Status
- (S)AE
- (S)AE Follow-up

• 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.

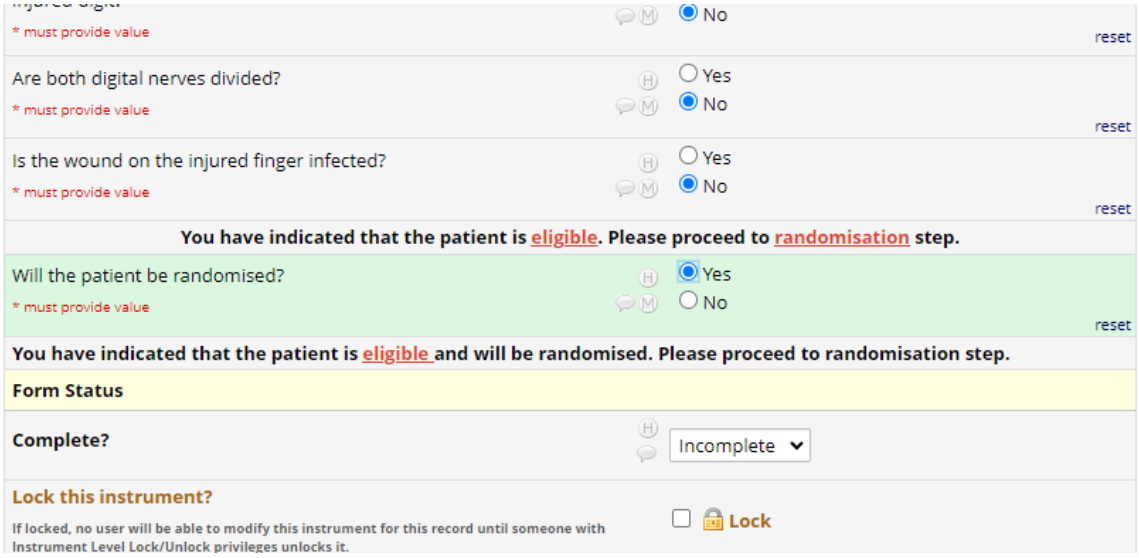
Printing REDCap instruments for completion on paper

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.

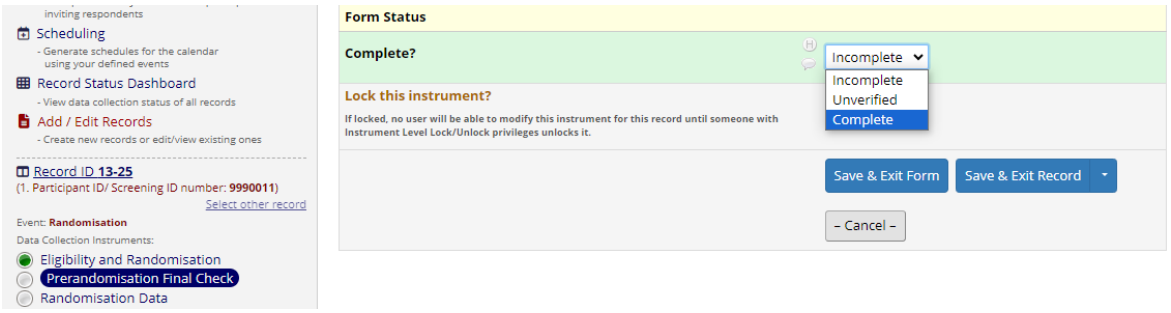


How to randomise on REDCap

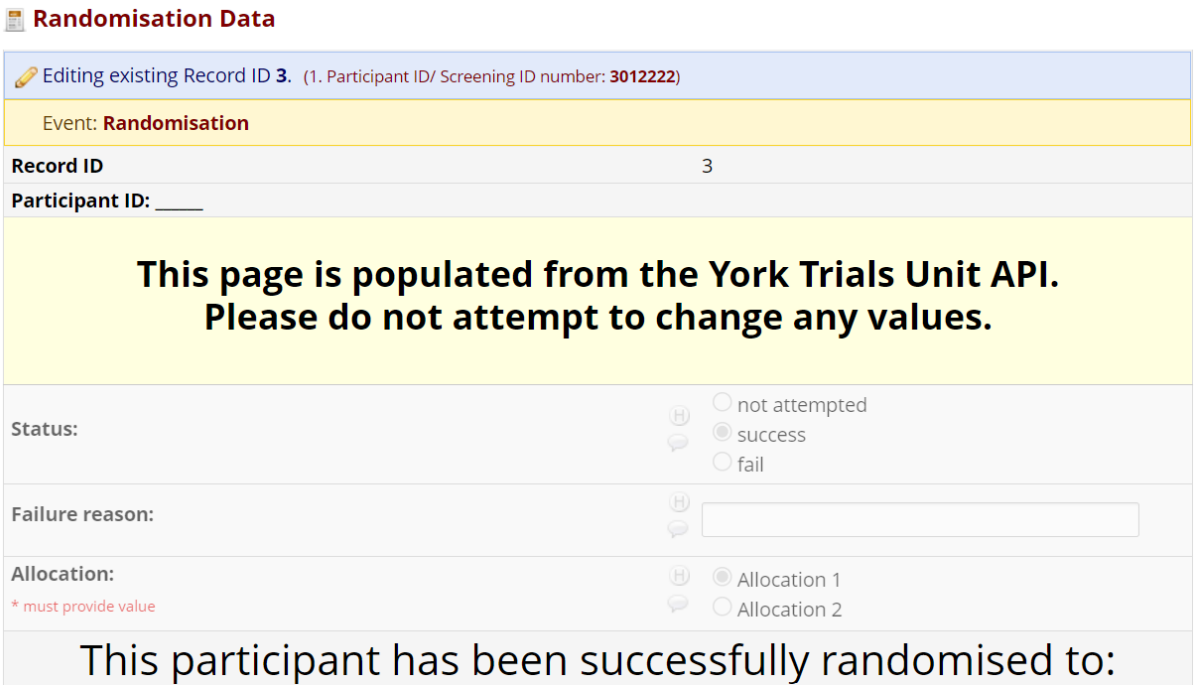
- Find the patient's record on REDCap; please ensure that you are using the correct record
- Complete the *Eligibility and Randomisation instrument* on REDCap, ensuring you select 'Yes' in response to the question "Will the patient be randomised?"
- Mark the Form Status as 'Complete'



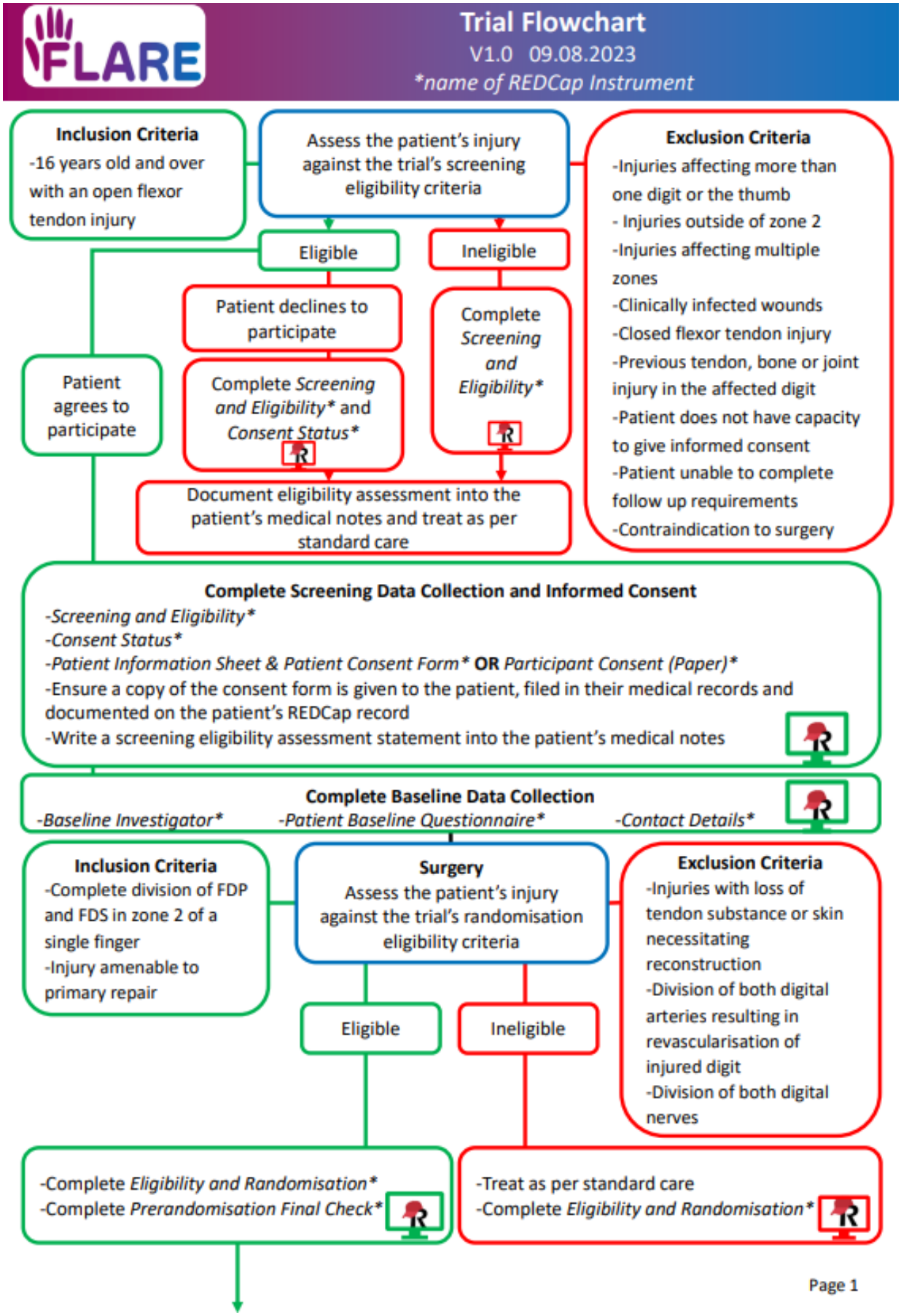
- Open the *Prerandomisation Final Check instrument* on REDCap, change the Form Status to 'Complete', and click 'Save and Exit Form'.

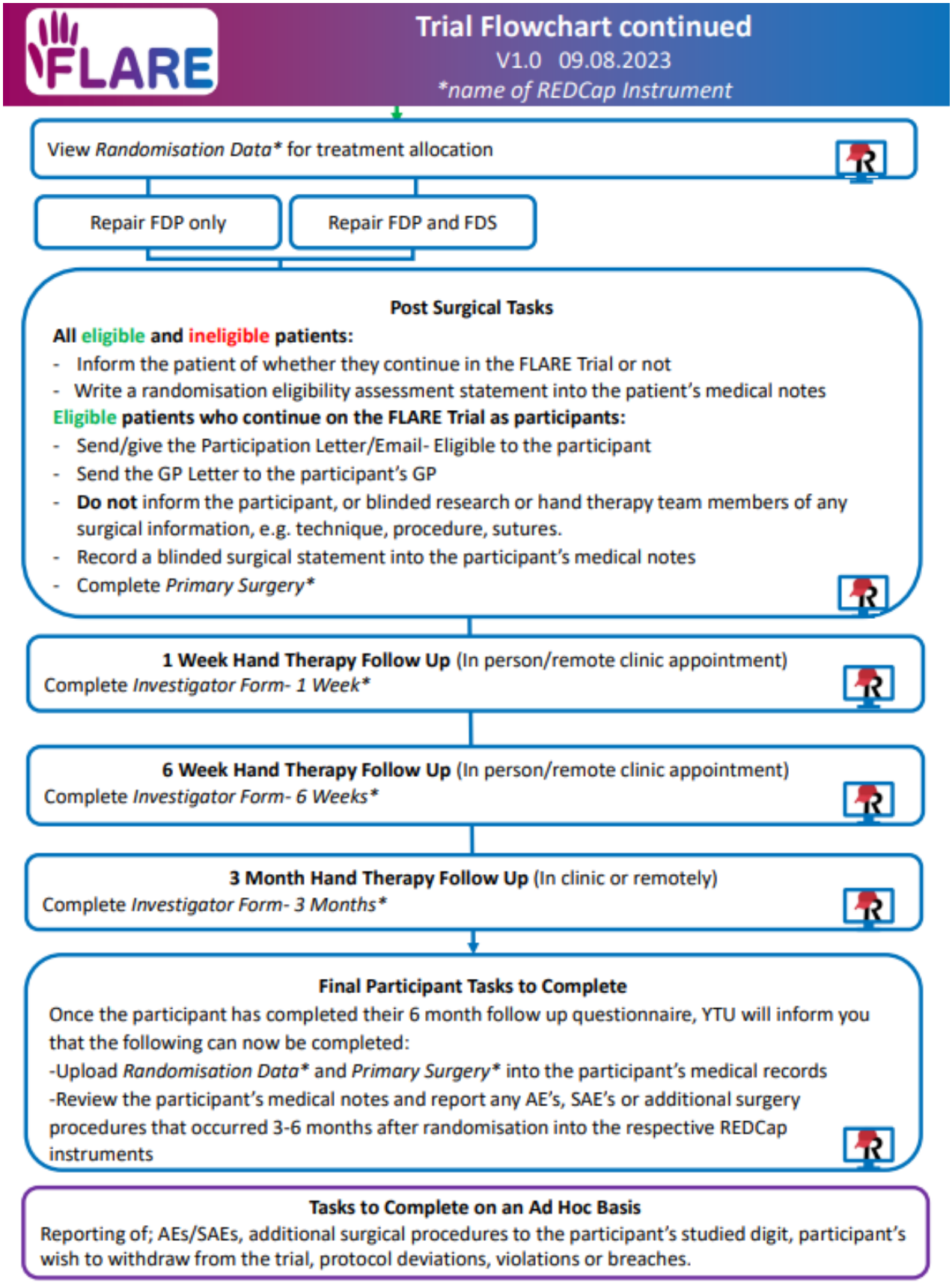


- Open the *Randomisation Data instrument* on REDCap to view the randomised treatment allocation


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:

21. Trial Flowchart





For further information on any of the tasks stated, please refer to the FLARE Trial Site Manual.

Page 2