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DISTAL RADIUS ACUTE FRACTURE TRIAL
CAST VS SPLINT

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DRAFT3-CASP
Distal Radius Acute Fracture Trial 3: Cast vs Splint

***S**ite **I**nitiation **V**isit Slides*

All site staff

DRAFT3 SIV Slides V1.0 06Dec2022

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Contents

- Introduction to the trial team
- Trial background and aims
- Trial design
- Inclusion/Exclusion criteria
- Patient pathway
- Electronic systems overview (Website/Database)
- DRAFT3-CASP Team contact details

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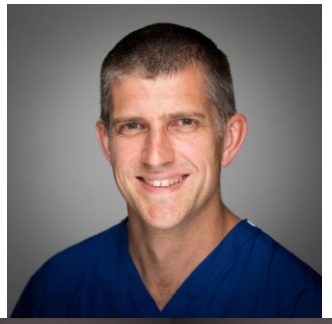
Trial Management Team

Sponsor	University Of Oxford
Funder	NIHR - HTA
Trial Management Team	Oxford Trauma, OCTRU
Chief Investigator	Professor Matt Costa
Trial Manager	Heather Barnes
Trial Administrator	Elli Cox
ISRCTN	66692543



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Trial Overview

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Background & Rationale

- Over 100,000 distal radius fractures in the UK each year
- 6% of all women, by the age of 80, will have sustained such a fracture
- For those patients whose fracture remains aligned, usual care is to provide the patient with a cast. The patient then has to return to hospital 4-6 weeks later to have this removed
- Recently, there has been some evidence that a removable wrist splint may provide the patient with the same support as a cast whilst their fracture heals.
- A splint can be removed by the patient themselves, which could be more convenient to patients and save money for the NHS.

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Trial Objectives

Aim:

The aim of this pragmatic, randomised non-inferiority trial is to compare the clinical and cost-effectiveness of a Cast with follow-up as per usual care versus a removable splint with discharge from ED.

Primary Objective:

Objective	Outcome Measure	Time point
To quantify and draw inferences on observed differences in function between treatment groups	Patient Reported Wrist Evaluation (PRWE)	3 months post-randomisation

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Trial Objectives

Secondary Objectives: To quantify and draw inferences on:

	≤ 2 weeks	≤ 7 weeks	3m	6m	12m
Wrist pain	✓				
Wrist function	✓	✓		✓	✓
Health-related quality of life (HRQoL)	✓		✓	✓	✓
Complication rate	✓	✓	✓	✓	✓
Resource implications			✓	✓	✓
Cost-effectiveness			✓	✓	✓

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Trial Design

Method	Multi-centre, two-group, randomised non-inferiority trial with parallel economic analysis and direct patient follow-up to 12 month post-randomisation.
Population	Patients aged 16 years and older with an acute fracture of the distal radius who, in the opinion of the treating clinician, do not require a manipulation of the fracture.
Intervention	Removable splint with discharge from ED
Sample Size	1894
Sites	At least 36 (At least 6 in pilot phase)

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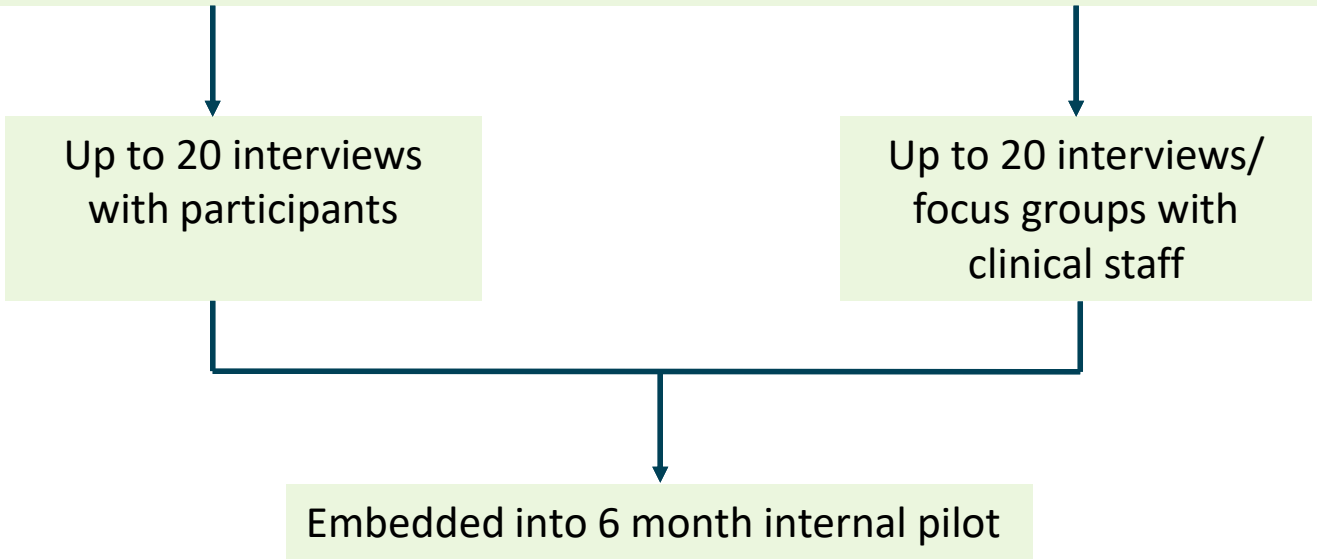
Treatments

Plaster cast
vs
Removable splint

Process evaluation

The acceptability of the potential treatment pathway involving immediate discharge/no planned follow-up will be explored both with participants and those involved in the clinical care of the participants involved in the trial



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Eligibility Criteria: Inclusion

- ✓ Participant is willing and able to give informed consent for participation in the study
- ✓ Aged 16 years or above
- ✓ Presenting with a fracture of the distal radius which, in the opinion of the treating clinician, does not require a manipulation of the fracture

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Eligibility Criteria: Exclusion

The participant may not enter the study if **ANY** of the following apply:

- Present to the research team more than 2 weeks post-injury
- The fracture is open (Gustilo and Anderson >1)
- They are unable to adhere to trial procedures e.g. patients with permanent cognitive impairment, or other concomitant severe injuries e.g. head injury

N.B. If a patient presents with a distal radius fracture to both wrists i.e. both wrists are eligible, the patient will be included but only one wrist will be randomised – whichever, in the clinician's opinion, is the worse injury. It is expected that the other eligible injured wrist will be treated in the same way.

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Recruitment target:

- **3.2 patients per month, per site**

Identifying participants:

- Patients will be identified in the Emergency Department
- After radiographic confirmation of a fracture the local clinical team will confirm the eligibility of the individual patient to participate
- Consent will be taken face to face via the eConsent form on REDCap
- The participant will complete the baseline questionnaires
- The participant will be randomised in ED and discharged/followed-up as per the local pathway depending on treatment allocation.

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Patient Pathway

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Trial Systems

Patient Information Sheet	Online and website
Screening	Online in REDCap
Consent	Online in REDCap
Baseline CRFs & Randomisation	Online in REDCap
Participant questionnaires	Sent from CTU- Options to complete via: • Text/SMS • Email • Telephone call • Postal
Data entry (site CRFs)	Online in REDCap
Delegation, Training and SIV Logs	Online in REDCap

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Screening
a patient >16 years old with a distal radius fracture is identified
Completed electronically on REDCap

↓

Consent form
Contact details form
Contact details check form
Consent to contact form*

↓

Baseline Questionnaires
Pre-Injury PRWE, Pre-Injury EQ-5D-5L, Post-Injury PRWE, Post-Injury EQ-5D-5L, PROMIS Upper Limb Physical Function, VAS Pain Score

Baseline demographics CRF

↓

Randomisation 1:1
Treatment CRF

- Completed by site staff
- Completed by site staff alongside participant
- Completed by participant

* Participants will only complete a consent to contact form if they have indicated on the consent form or it has been indicated on the screening form that they wish to take part in the qualitative interviews.

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Randomisation 1:1
Treatment CRF

Cast

With follow-up as per usual care at the treating centre

Removable Splint

With discharge from ED

Follow-Up
Completed remotely by participant

Days 1, 3, 5, 7, 10 and 14: VAS Pain Score
Week 1: EQ-5D-5L
Week 2: Day 14 Follow-up CRF, Complications*
Week 7: PRWE, Week 7 Follow-up CRF, Complications*
3 Months: PRWE, EQ-5D-5L, PROMIS Upper Limb Physical Function, 3 Month Follow-up CRF, Complications*, Health Economics Questionnaire
6 and 12 months: PRWE, EQ-5D-5L, PROMIS Upper Limb Physical Function, Complications*, Health Economics Questionnaire

***AD Hoc CRFs**
- **SAE form**
- **Protocol deviation form**
- **Withdrawal/death form**

Completed by site or trial team online via REDCap

***Complications**

If a participant indicates on a complications form that they have had an operation, the central trial team may contact the site to ask them to complete the complications form with the type of operation received and the associated OPCS-4 code.

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Electronic Systems Overview

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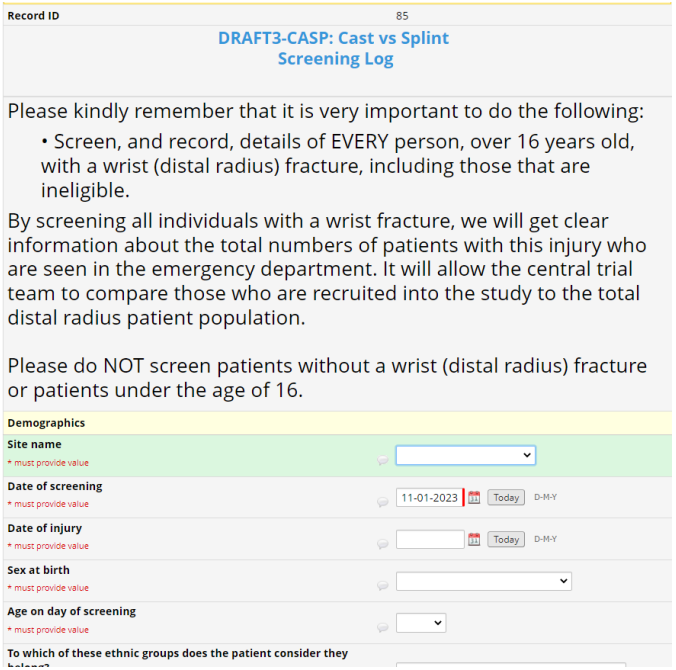
Reminder

Access to website and Passwords
Every team member who has access to REDCap will have their own individual password
Please do **not** share your password with anyone
Access to the screening -> randomisation website will be through a generic password which will be given upon greenlight
If you are having problems logging in, please contact the trial team.
If a new member of the team requires access, please contact the trial team.
At least one member of the site team will need to be given access to RRAMP (randomisation system) in case of website randomisation failure.

Screening to randomisation



Record ID 85

DRAFT3-CASP: Cast vs Splint
Screening Log

Please kindly remember that it is very important to do the following:

- Screen, and record, details of EVERY person, over 16 years old, with a wrist (distal radius) fracture, including those that are ineligible.

By screening all individuals with a wrist fracture, we will get clear information about the total numbers of patients with this injury who are seen in the emergency department. It will allow the central trial team to compare those who are recruited into the study to the total distal radius patient population.

Please do NOT screen patients without a wrist (distal radius) fracture or patients under the age of 16.

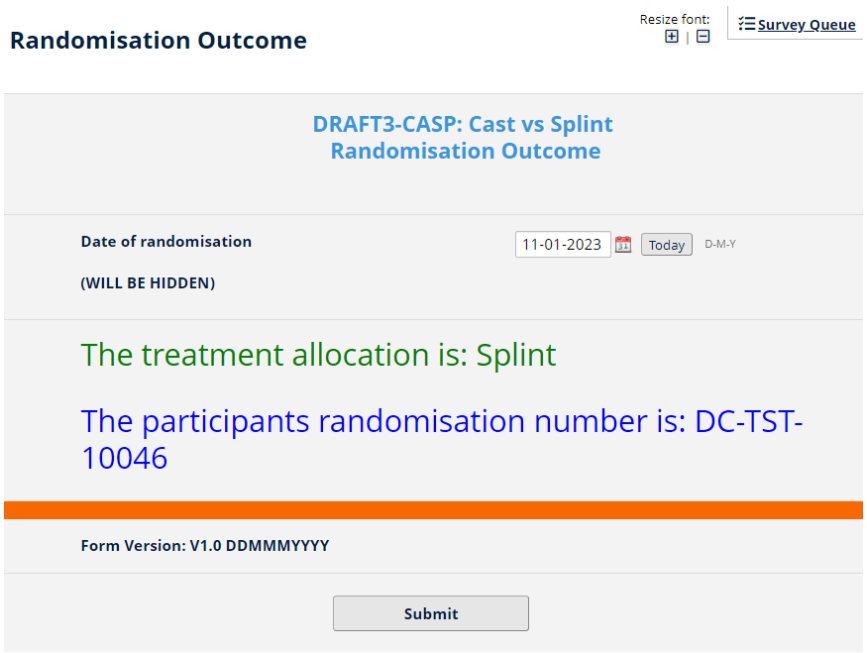
Demographics

Site name * must provide value	
Date of screening * must provide value	11-01-2023 Today D-M-Y
Date of injury * must provide value	Today D-M-Y
Sex at birth * must provide value	
Age on day of screening * must provide value	
To which of these ethnic groups does the patient consider they	

After entering your password into the DRAFT3 website www.draft3casp.org– Enrol a new patient you will be redirected to the screening website.

When screening is completed, if patient is eligible, you will be automatically routed to each form in order until randomisation is complete.

Screening to randomisation



Randomisation will occur via REDCap which communicates directly with our randomisation system RRAMP.

There will be a slight delay when randomising- please be patient RRAMP returns allocation and Study ID to REDCap

Randomisation occurs as final step after all baseline questionnaires have been complete

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Site CRFs overview

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----Baseline Day 0---------

Completed by Staff

Screening Form
Consent form (Completed with patient)
Contact details (Completed with participant)
Contact details check (Completed with participant)
Consent to contact (Completed with participant)

Completed by participant

PRWE (pre-injury)
EQ-5D-5L (pre-injury)
PRWE (today)
EQ-5D-5L (today)
PROMIS Upper Limb Physical Function
VAS Pain Score
Baseline CRF

----Randomisation Day 0---------

Completed by staff

Randomisation form
Randomisation Check form
Randomisation outcome form
Treatment CRF

Before being discharged **ALL** participants will be given a rehabilitation booklet. This will be recorded on the Treatment CRF.

Participants can also access this via the study website if they prefer to have an electronic copy

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Protocol Deviations

Any deviations from the protocol or trial procedures need to be reported on REDCap in a Protocol Deviation form.

Protocol Deviation	Action for Site
Patient recruited to trial in violation of eligibility criteria	Training provided to RA and PI responsible for assessing eligibility.
The participant receives the wrong treatment allocation (crossover)	Treatment CRF in REDCap. Training provided to site team.
Missing/incorrect data	Training provided to site team/query incorrect data with site
Staff member randomising/ consenting patient without delegation log entry authorising them to undertake task	Training provided to site team if frequent deviations at a site occur.

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Complications

- Foreseeable SAEs and adverse events not defined as serious that are related to the interventions will be recorded by participants but <u>will not need to be reported immediately</u>
- These events will be recorded on patient-reported questionnaires.
- If patient indicates on the complications questionnaire that they have had an operation, the site will be prompted to complete the end of the form with the type of operation the participant had and the OCPS-4 codes

Foreseeable adverse events include:

- Pressure sore (grade II or above) identified while the splint/cast is being worn
- Nerve damage identified after the injury but before the splint/cast is removed
- The need for further manipulation of the fracture in the first six weeks after randomisation
- The need for surgical intervention for the fracture

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Serious Adverse Events

SAEs are likely to be very rare and highly unlikely to occur as a result of the treatments in this trial.

A serious adverse event (SAE) is any untoward medical occurrence that:

- Results in death
- Is life-threatening
- Requires inpatient hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability/incapacity
- Consists of a congenital anomaly or birth defect.

Other ‘important medical events’ may also be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

Serious Adverse Events

If an SAE has been identified, notify the DRAFT3-CASP Trial Office by email at draft3-casp@ndorms.ox.ac.uk at the earliest opportunity and within 24 hours of becoming aware of the event.

You must also ensure there is appropriate follow up of the patient until the event is resolved.

Using the Serious Adverse Event form in REDCap, the local research team should complete and report all SAEs which are not listed in the protocol (see previous slides). The Principal Investigator or delegated person should review these and sign off.

The SAE form must be submitted within 24 hours of becoming aware of SAE and the DRAFT3-CASP CTU must be informed via email

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Withdrawal/Death

Patient Withdrawal- please complete a Withdrawal/ Death CRF in REDCap

Withdrawal may be requested by participants, next of kin or very occasionally the treating clinician.

Withdrawals are anticipated to be rare and patients will only be withdrawn as a last resort. Please call or email us to discuss prior to withdrawing a patient.

*Participants will be aware that if they do decide to withdraw, any data collected to the point of withdrawal will be retained for the study

Patient Death- please complete a Withdrawal/ Death CRF in REDCap

Upon learning of a patients death, please enter as much information as is known in the CRF and please inform the CTU via email so all follow-ups can be stopped.

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Delegation Log
Training Log
SIV Log

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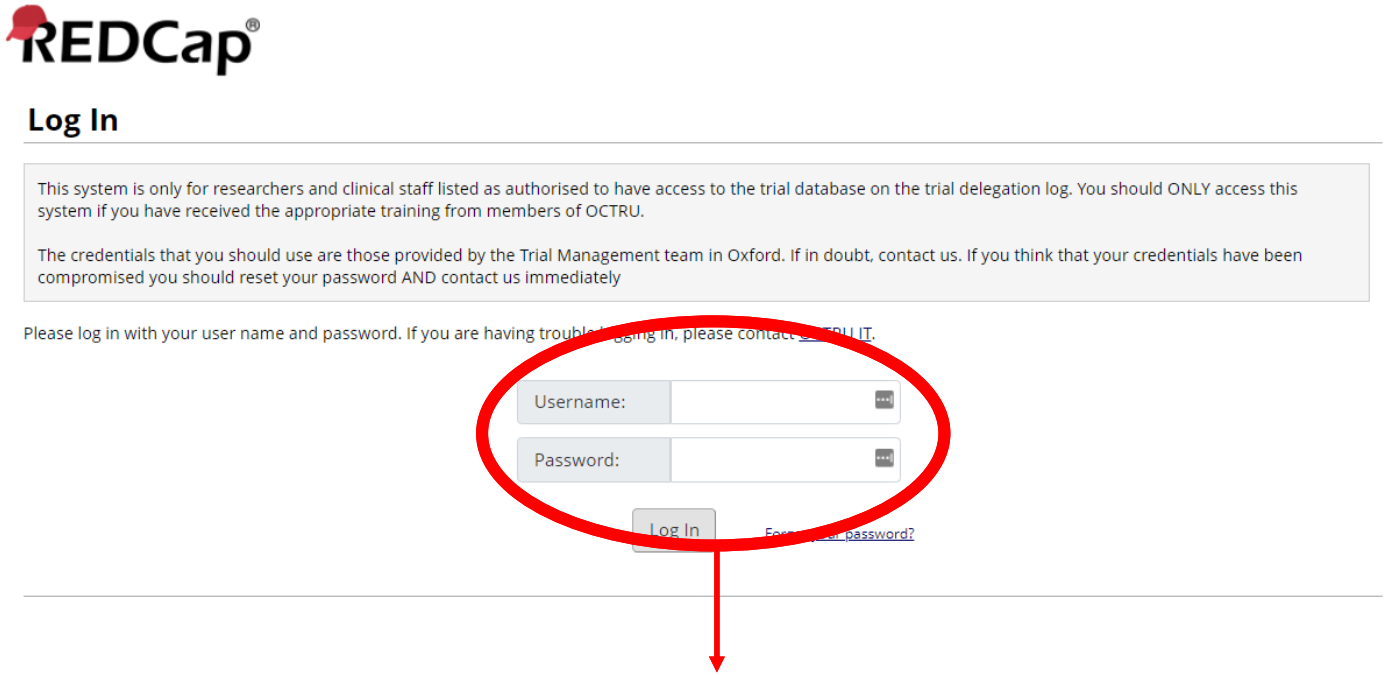
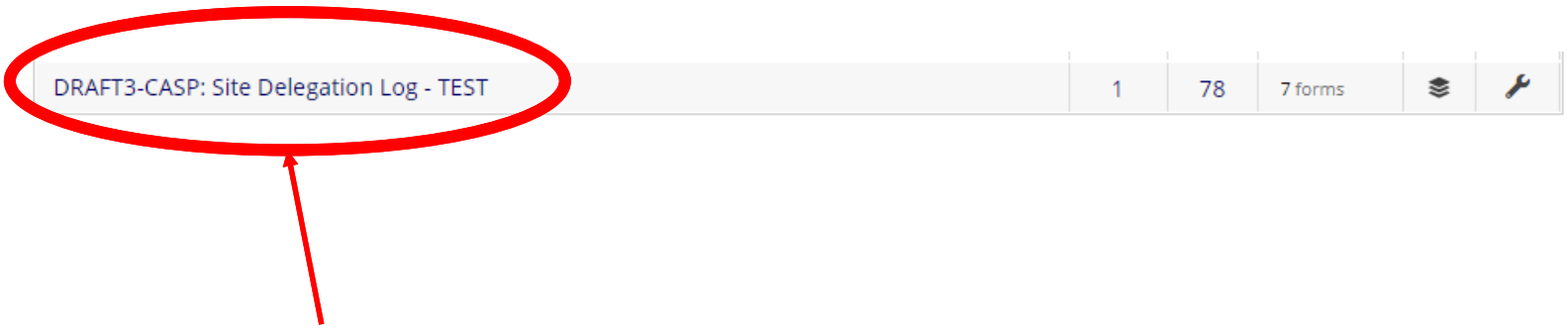
https://redcap-cctr.octru.ox.ac.uk/redcap_v10.6.17/index.php?pid=201



1. Log in to REDCap using personal log-in details

REDCap Overview 1/6



2. Select ‘DRAFT3-CASP: Site Delegation Log’ Project

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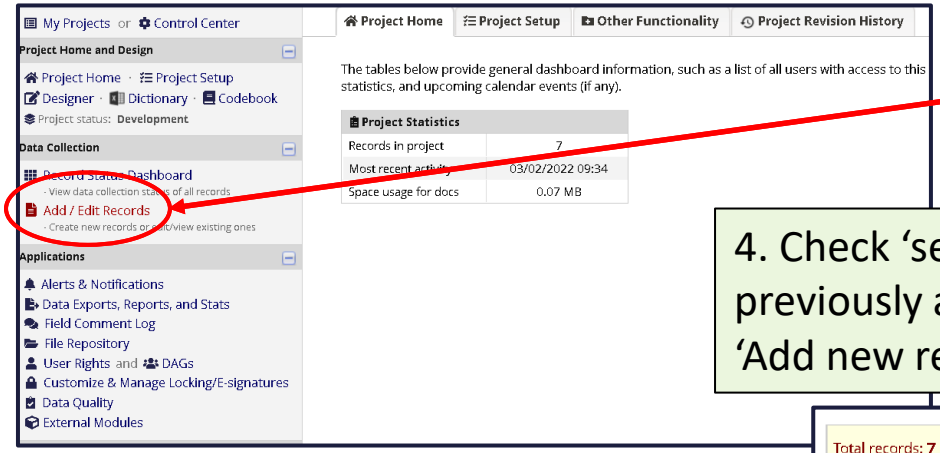
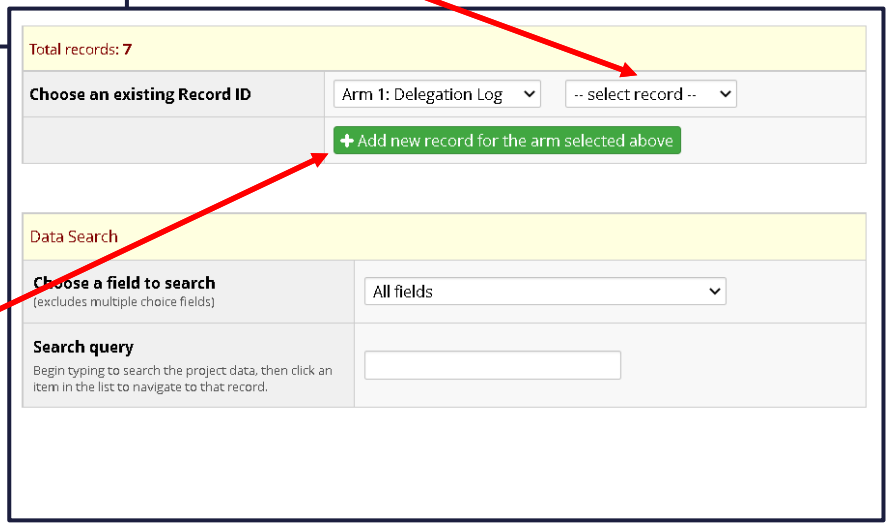
REDCap Overview 2/6



3. Select 'Add/Edit Records' from left hand menu

4. Check 'select record' If your site has been previously added – select your site and then select 'Add new record for arm selected above'



5. If your site has NOT been previously added – leave 'select record' blank and select 'Add new record for arm selected above'

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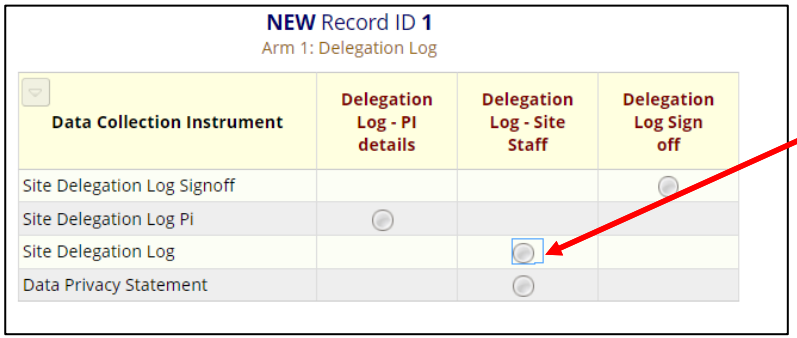
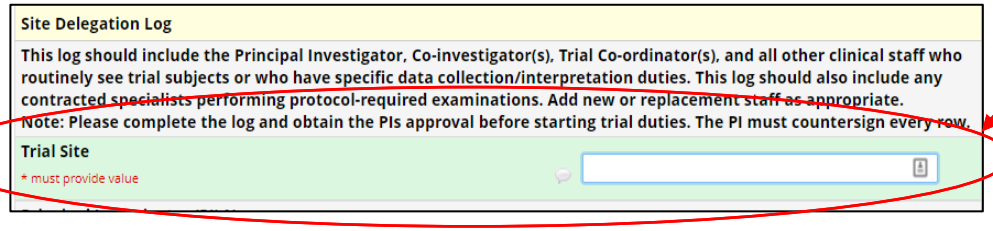
REDCap Overview 3/6

If your site **HAS NOT** been previously added



1. First staff member to log in will select 'Delegation Log'

2. Complete 'Trial Site' text as you wish name to appear in REDCap

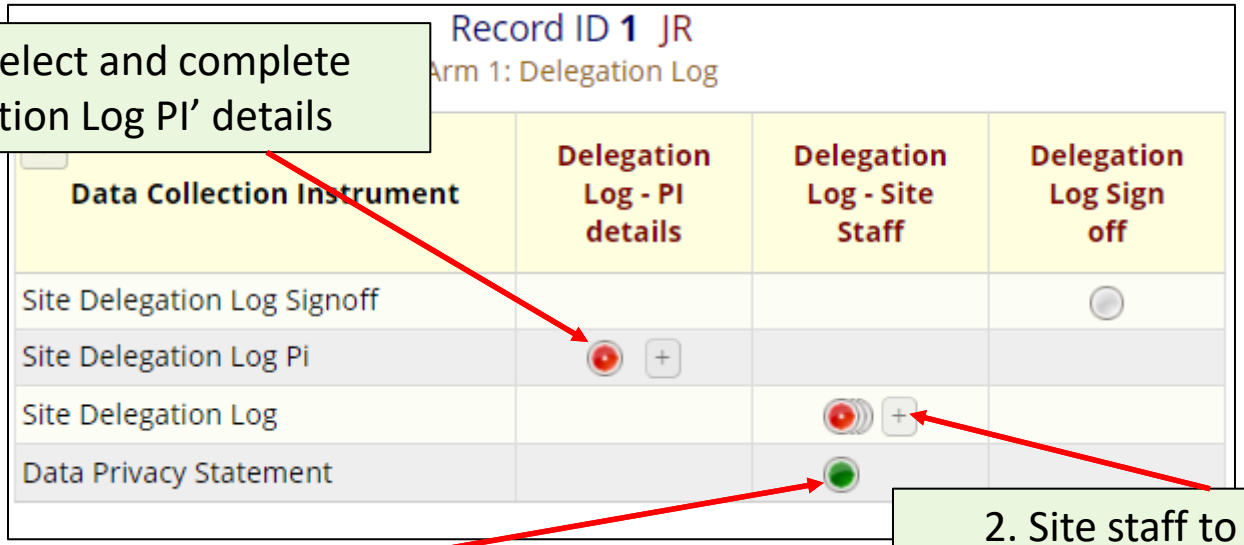


3. Continue as per instructions on next 3 slides

REDCap Overview 4/6

If your site **HAS** been previously added

1. PI to select and complete ‘Delegation Log PI’ details



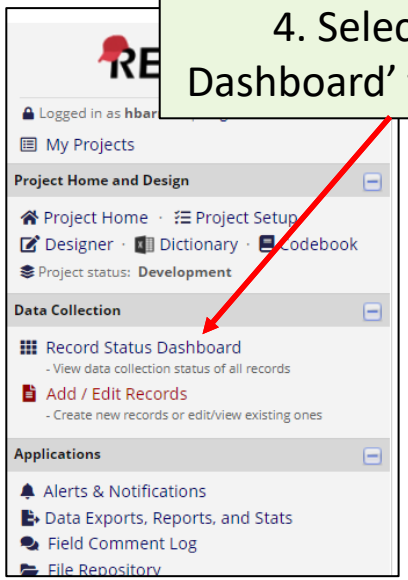
2. Site staff to select and complete ‘Site delegation log’ **Including PI**

Select + to add new instance

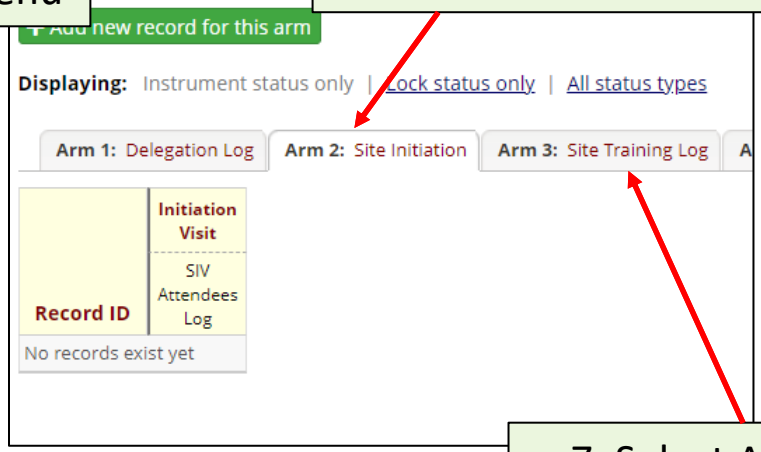
3. One team member only to complete ‘Data Privacy Statement’

REDCap Overview 5/6

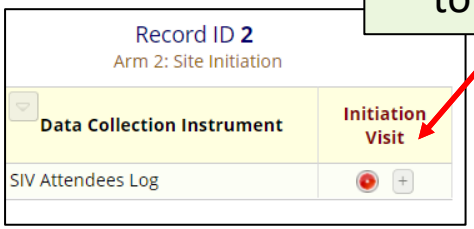
4. Select 'Record Status Dashboard' from left hand menu



5. Select Arm 2 – Site Initiation

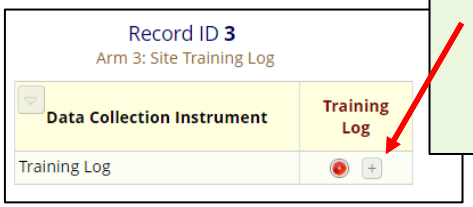


6. All staff attending SIV to complete this log

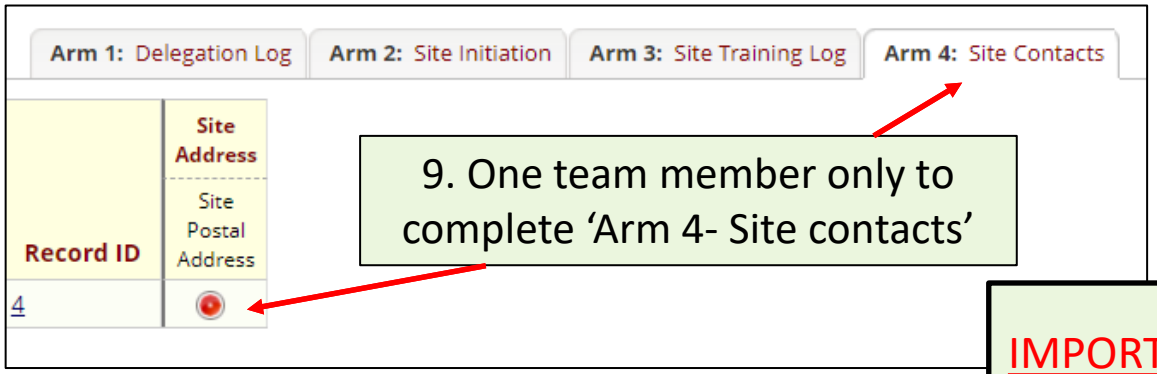


7. Select Arm 3 ' Site Training Log'

8. All staff wishing to have access to REDCap to complete this form



REDCap Overview 6/6



9. One team member only to complete 'Arm 4- Site contacts'

10. Please inform DRAFT3-CASP team when staff forms are completed

IMPORTANT NOTE

When completing REDCap forms staff must be signed in with their OWN USER DETAILS.

If this procedure is not followed site staff may be asked to complete forms again.

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PI Responsibilities

- Must have completed GCP training
- Overall responsibility for activity at this site
- Regular communication with CTU
- Ensure staff are suitably trained for responsibilities delegated at start of trial & throughout (regular delegation log updates as needed)
- Advise CTU of changes to key research staff (PI, lead RA/RN)

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Site Payments

- £40 per patient recruited appropriately
- Payment made after all required data has been provided to the Sponsor (12 months) and any reasonable queries have been resolved
- NIHR Portfolio support

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Additional Information

iPads available	A limited number of iPads are available for sites who do not have access to an Oxford Trauma iPad already
NIHR aPI Scheme	Staff members who meet the relevant criteria can apply to take part in the NIHR aPI scheme (1 per site, can be changed after 6 months)

DRAFT3-CASP Team Contact

- Chief Investigator - Matt Costa
- Trial Manager – Heather Barnes
- Trial Administrator – Elli Cox

  ✉ draft3-casp@ndorms.ox.ac.uk

  ☎ 01865 223113

- Twitter:

  @Draft3C @Oxford_Trauma @NDORMS

Mailing Address

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Headley Way
Oxford, OX3 9DU

Thank you

Any Questions?