

DRAFT3-CASP REDCap Delegation Log Guide

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Contents

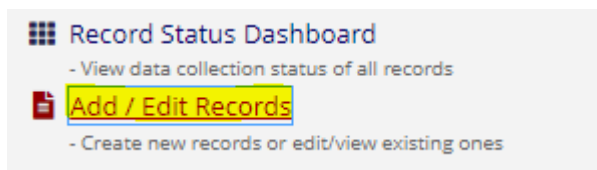
Completing a normal delegation log record	1
Completing a PI delegation log record.....	5
Completing the data privacy statement	6
Completing a training log record	7



Completing a normal delegation log record

Before anyone does any work on the trial, they must be signed off to do those tasks by the PI in the delegation log. The PI must also complete a normal delegation log record and sign this off in addition to the PI delegation log record.

If you are the first person at your site to create a delegation log record, please click Add/Edit Records on the left-hand side of the screen.



To make the first delegation log record choose Arm 1: Delegation Log and then click the green +Add new record for the arm selected above button.

Total records: 5 / In group: 0

Choose an existing Record ID Arm 1: Delegation Log -- select record --

+ Add new record for the arm selected above

You can then get into the actual delegation log by clicking the button as highlighted below.

NEW Record ID 3075-1

Arm 1: Delegation Log

Data Collection Instrument	Delegation Log - PI details	Delegation Log - Site Staff	Delegation Log Sign off
Site Delegation Log Signoff			<input type="radio"/>
Site Delegation Log Pi	<input type="radio"/>		
Site Delegation Log		<input checked="" type="radio"/>	
Data Privacy Statement		<input type="radio"/>	

If you are not the first person at your site to create a delegation log record, please click Record Status Dashboard on the left-hand side of the screen.

Record Status Dashboard
- View data collection status of all records

Add / Edit Records
- Create new records or edit/view existing ones

You can then either make a new record by clicking the small + next to the coloured circle under Site Delegation Log or by clicking the Record ID number and then the + Add new button at the bottom of the Repeating Instruments. Do not use the green button at the top of this page.

+ Add new record for this arm

Displaying: Instrument status only | [Lock status only](#) | [All status types](#)

Arm 1: Delegation Log | Arm 2: Site Initiation | Arm 3: Site Training Log | Arm 4: Site Contacts

Record ID	Delegation Log - PI details	Delegation Log - Site Staff		Delegation Log Sign off
	Site Delegation Log Pi	Site Delegation Log	Data Privacy Statement	Site Delegation Log Signoff
3075-2	<input type="radio"/>	<input checked="" type="radio"/> +	<input type="radio"/>	<input type="radio"/>

or

[+ Add new record for this arm](#)

Displaying: [Instrument status only](#) | [Lock status only](#) | [All status types](#)

[Arm 1: Delegation Log](#) | [Arm 2: Site Initiation](#) | [Arm 3: Site Training Log](#) | [Arm 4: Site Contacts](#)

Record ID	Delegation Log - PI details	Delegation Log - Site Staff		Delegation Log Sign off
	Site Delegation Log Pi	Site Delegation Log	Data Privacy Statement	Site Delegation Log Signoff
3075-2	<input type="radio"/>	<input checked="" type="radio"/> +	<input type="radio"/>	<input type="radio"/>

Then...

Record ID 3075-2

Arm 1: Delegation Log

Data Collection Instrument	Delegation Log - PI details	Delegation Log - Site Staff	Delegation Log Sign off
Site Delegation Log Signoff			<input type="radio"/>
Site Delegation Log Pi	<input type="radio"/>		
Site Delegation Log		<input checked="" type="radio"/> +	
Data Privacy Statement		<input type="radio"/>	

Repeating Instruments

Site Delegation Log			
Delegation Log - Site Staff (Arm 1: Delegation Log)			
(1)			
1	<input checked="" type="radio"/>		: -
+ Add new			

Any of these options will take you to the delegation log. Please enter the site name if it isn't already there. You will then need to complete the PI's name, your details and then tick all duties you may be responsible for during the trial.

Site Delegation Log	
This log should include the Principal Investigator, Co-investigator(s), Trial Co-ordinator(s), and all other clinical staff who routinely see trial subjects or who have specific data collection/interpretation duties. This log should also include any contracted specialists performing protocol-required examinations. Add new or replacement staff as appropriate. Note: Please complete the log and obtain the PIs approval before starting trial duties. The PI must countersign every row.	
Trial Site <small>* must provide value</small>	<input type="text"/>
Principal Investigator (PI) Name: <small>* must provide value</small>	<input type="text"/>
Full Name <small>* must provide value</small>	<input type="text"/>
Trial Role <small>* must provide value</small>	<input type="text" value="v"/>
E-Mail Address <small>* must provide value</small>	<input type="text"/>
Phone Number <small>* must provide value</small>	<input type="text"/>
General Duties <small>* must provide value</small>	<input type="text"/>
<input type="checkbox"/> Leading/briefing the study team	
<input type="checkbox"/> Informed consent discussion	
<input type="checkbox"/> Taking signed informed consent	
<input type="checkbox"/> Screen patients	
<input type="checkbox"/> Confirm eligibility	
<input type="checkbox"/> Randomise study participants	
<input type="checkbox"/> Medical/Physical examination	
<input type="checkbox"/> Conduct study visit procedures	
<input type="checkbox"/> SAE form completion and reporting	
<input type="checkbox"/> SAE safety review (assessment of causality) & final sign off	
<input type="checkbox"/> Maintain Site Files/documents during study	
<input type="checkbox"/> Preparing documents for archiving	
<input type="checkbox"/> Main contact for monitors	
<input type="checkbox"/> CRF completion/resolution of data queries	
<input type="checkbox"/> Review and sign off on source data and CRFs (must be principal investigator or sub-investigator)	
<input type="checkbox"/> Perform study related assessments	
<input type="checkbox"/> Administer trial intervention	
<input type="checkbox"/> Sample collection/processing	

After this you should sign and initial the log (**this must be done under your own REDCap login and not someone else's**) and enter today's date in the 'Date of Duties From:' box. Please do not fill in the 'Date of Duties To:' as this will need to be done if/when you leave the trial. We do not need a copy of your CV (unless you are the PI or co-PI) but please ensure you tick this box to prove that you do have one. Every delegation log must then be countersigned by the PI to confirm that they are happy with all of the information provided in the log and with the duties that have been selected.

Signature <small>* must provide value</small>		Add signature
Usual Initials <small>* must provide value</small>		Add signature
Date of Duties From <small>* must provide value</small>		<input type="text"/> Today D-M-Y
Date of Duties To:		<input type="text"/> Today D-M-Y
CV <small>* must provide value</small>		<input type="radio"/> Yes <input type="radio"/> No reset
Principal Investigator Signature <small>* must provide value</small>		Add signature
Date of PI signature <small>* must provide value</small>		<input type="text"/> Today D-M-Y
OCTRU-OT-009_V5.0_20Sep2019 Effective Date 27Sep2019		
Form Status		
Complete?		Incomplete
		Save & Exit Form Save & ...

Completing a PI delegation log record

A PI delegation log record must be created by the main PI at a site, if this changes during the trial, the new one must complete one too.

The PI delegation log can be found under Arm 1 by clicking the button as highlighted below. If no-one has created a record for your site yet you can follow step one of completing a normal delegation log record above to reach this point.

NEW Record ID 3075-3 Arm 1: Delegation Log

	Delegation Log - PI details	Delegation Log - Site Staff	Delegation Log Sign off
Data Collection Instrument			
Site Delegation Log Signoff			<input type="radio"/>
Site Delegation Log Pi	<input checked="" type="radio"/>		
Site Delegation Log		<input type="radio"/>	
Data Privacy Statement		<input type="radio"/>	

Please fill in the site (if it does not already appear), full name and Start Date. You must sign the log and confirm that you have a CV. We will need a copy of this CV if we do not already.

Site	<input type="text"/>
Name of Principal Investigator <small>* must provide value</small>	<input type="text"/>
Start Date <small>* must provide value</small>	<input type="text"/> Today D-M-Y
End Date	<input type="text"/> Today D-M-Y
Signature <small>* must provide value</small>	Add signature
CV <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No
<small>reset</small>	
OCTRU-OT-009_V5.0_20Sep2019	
Effective Date 27Sep2019	
Form Status	
Complete?	Incomplete ▾
<input type="button" value="Save & Exit Form"/> <input type="button" value="Save & ..."/> <input type="button" value="-- Cancel --"/>	

Completing the data privacy statement

This must be read and marked as complete by one of your site staff to indicate to us that you understand and accept it.

It can be accessed by clicking the button as highlighted below.

NEW Record ID 3075-1

Arm 1: Delegation Log

<input type="button" value="▼"/>	Data Collection Instrument	Delegation Log - PI details	Delegation Log - Site Staff	Delegation Log Sign off
	Site Delegation Log Signoff			<input type="radio"/>
	Site Delegation Log Pi	<input type="radio"/>		
	Site Delegation Log		<input type="radio"/>	
	Data Privacy Statement		<input type="radio"/>	

Please read the entire statement and then click the dropdown and change it to complete before saving and exiting.

If you want to ask about your rights, or have any other questions or complaints about how the Study Sponsor has handled your Personal Data, you can contact the Study Sponsor at any time via Heather.house@admin.ox.ac.uk. Should you wish to contact the Data Protection Officer of the Study Sponsor you may do so via data.protection@admin.ox.ac.uk.

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

OCTRU-OT-009_V5.0_20Sep2019
Effective Date 27Sep2019

Form Status

Complete? Complete

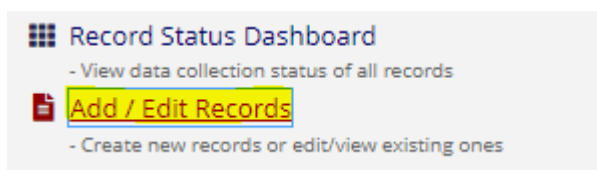
Save & Exit Form Save & ...

-- Cancel --

Completing a training log record

Only staff members who have a completed delegation record AND training record will be able to access the patient databases (DRAFT3-CASP Study Data and DRAFT3-CASP Screening & Consent) as well as the Study Information Management System (SIMS).

If you are the first person at your site to create a training log record, please click Add/Edit Records on the left-hand side of the screen.



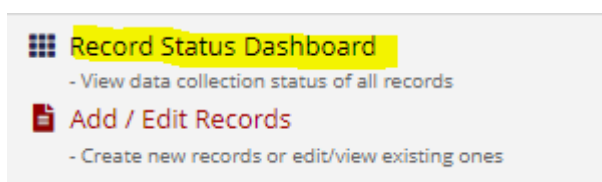
To make the first training log record choose Arm 3: Site Training Log and then click the green +Add new record for the arm selected above button.

Total records: 5 / In group: 0

Choose an existing Record ID Arm 3: Site Training Log -- select record --

+ Add new record for the arm selected above

If you are not the first person at your site to create a delegation log record, please click Record Status Dashboard on the left-hand side of the screen.



You can then either make a new record by clicking the small + next to the coloured circle under Training Log or by clicking the Record ID number and then the + Add new button at the bottom of the Repeating Instruments. Do not use the green button at the top of this page.

+ Add new record for this arm

Displaying: [Instrument status only](#) | [Lock status only](#) | [All status types](#)

[Arm 1: Delegation Log](#)
[Arm 2: Site Initiation](#)
[Arm 3: Site Training Log](#)
[Arm 4: Site Contacts](#)

Record ID	Training Log
3075-1	 

or

+ Add new record for this arm



Displaying: [Instrument status only](#) | [Lock status only](#) | [All status types](#)

[Arm 1: Delegation Log](#)
[Arm 2: Site Initiation](#)
[Arm 3: Site Training Log](#)
[Arm 4: Site Contacts](#)


Record ID	Training Log
3075-1	 

Then...

Record ID **3075-1**
Arm 3: Site Training Log

Data Collection Instrument	Training Log
Training Log	 

Repeating Instruments

Training Log		
Training Log (Arm 3: Site Training Log)		
(1)		
1		-
+ Add new		

Any of these options will take you to the training log. Please enter the site name if it isn't already there and the date. Please then fill in the Trainee details with your name and role and tick the Applications you were trained in. Please then sign this section. If you were trained at the SIV tick Yes under the Trainer details, you should also create an SIV log record (Arm 2). If you were trained from a member of your team using the SIV slides, then tick no to this and type "N/A – trained from SIV slides" in the Name of Trainer box that will pop up. You do not need to sign this section.

Centre	<input type="text"/>
Date	<input type="text"/> Today D-M-Y
Trainee	
First Name	<input type="text"/>
Last Name	<input type="text"/>
Role	<input type="text" value="v"/>
Application	<input type="checkbox"/> REDCap Screening Log (Data collection) <input type="checkbox"/> REDCap Delegation Log/Training Log <input type="checkbox"/> REDCap Site Forms (SAE/Protocol Deviation etc) <input type="checkbox"/> Other
Signature	
Add signature	
Trainer Details	
Trained at SIV	<input type="radio"/> Yes <input type="radio"/> No reset
Form Status	
Complete?	<input type="text" value="Incomplete"/>
<input type="button" value="Save & Exit Form"/> <input type="button" value="Save & ..."/>	
<input type="button" value="-- Cancel --"/>	