



## Global Evaluation of Cholecystectomy

## Knowledge and Outcomes



An international prospective cohort study on cholecystectomy

REDCap guide for Mini-team members





GECXO

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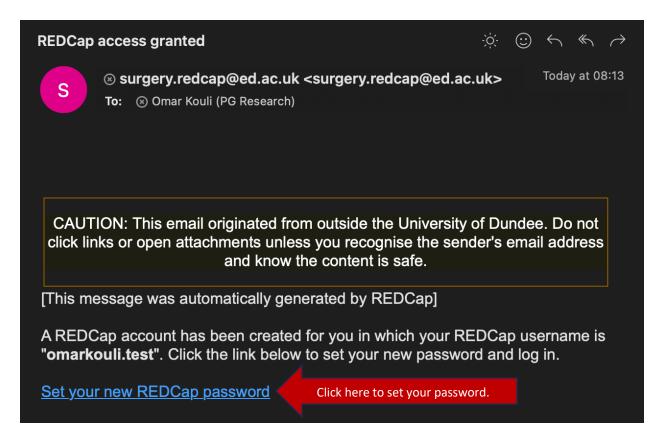




## SETTING UP YOUR REDCAP ACCOUNT

#### Step 1: REDCap account creation email

You will be sent a REDCap login creation email titled "REDCap access granted". Please note that this email will be sent to the email you supplied your hospital lead to fill in for you. This email might have been sent to your junk/spam folder, so please check there as well. The email will contain your username and a link to set up your new password (the link can be accessed by clicking on "Set your new REDCap password").





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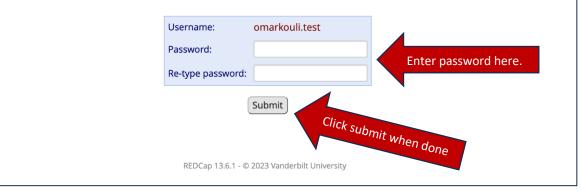
#### Step 2: Setting your password

Once you click on the link to set your new REDCap password, you will be redirected to the REDCap webpage to create your password. You will see your username in the dialog box. Click in the 'password' field to set your password. Your new password entered must be AT LEAST 9 CHARACTERS IN LENGTH and must consist of AT LEAST one lower-case letter, one upper-case letter, and one number. Once you enter and retype your password, click the "submit" button.

# REDCap

#### Set Your Password

Your password has not been set yet or has been reset. You will need to set your password here to whatever value you wish. Please enter your desired password below and click the 'Submit' button. Once your password has been set, you may use it with your username whenever you log in to REDCap. Please make sure that you write down or remember your new password for future use. The new password entered must be AT LEAST 9 CHARACTERS IN LENGTH and must consist of AT LEAST one lower-case letter, one upper-case letter, and one number.











## **ADDING NEW PATIENT DATA ON REDCAP**

#### Step 3: Accessing your project

Once you have submitted your password, this takes you to the REDCap welcome page. Click on the "My Projects" tab on the top left-hand corner. You will now see the projects you have access to. Click on the "GECKO – Data Collection" project to enter your details, your team details and complete the site survey.

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REDCap	Home	🗐 My Proje	ects 1-Cl	ck "My	projects"		P Messenger								Logged in as weehan.gecko.test	e Profile	🕞 Log out
					p projects to whi ur projects, visit			ccess. Click the projection of	ect title to	open the	e project	. <u>Read more</u> T	o revie	w which			
			My Projects	<b>D</b>	rganize 📄 Colla	pse All				Filter	r project	s by title	×				
			Project Title							Records	Fields	Instruments	Туре	Status			
	GECKO - Data Collection								D	0	172	8 forms		×			
					2-Clic,	k on G	ĨЕСКО - Da	ata Collection	iity	7							

#### Step 4: Record Status Dashboard

Once you are in the "GECKO - Data Collection" project, click on the "Record Status Dashboard" to access the forms you require to fill.

REDCap	GECKO - Data C	ollection	PID 90	
<ul> <li>Logged in as weehan.gecko.test</li> <li>Log out</li> </ul>	A Project Home			
<ul> <li>My Projects</li> <li>REDCap Messenger</li> <li>Contact REDCap administrator</li> </ul>			shboard information, such as a l ents (if any).	list of all users with acces
Project Home and Design	Current Users	-	Project Statistics	
Project Home · E Codebook Project status: Development	User	Expires	Records in project	Total: 0 / In group: 0
Data Collection — test	adermanis.gecko	never	Most recent activity	21-07-2023 17:17
Record Status Dashboard     View data collection status of all re	rna.gecko m Turna)	never	Space usage for docs	0.20 MB
- view data collection status of all re  Add / Edit Records  - Create new records or edit/view existing over	dbadran.gecko (Dania Badran)	never		
Show data collection instruments	egriffiths.gecko (Ewen Griffiths)	never		
Applications    Field Comment Log	eharrison (Ewen Harrison)	never		
Help & Information	hspiers.gecko (Harry Spiers)	never		
<ul> <li>Help &amp; FAQ</li> <li>Video Tutorials</li> </ul>	jbuchanan.gecko (John Buchanan)	never		
C Suggest a New Feature	jsmith.gecko (James Halle-Smith)	never		
🖂 Contact REDCap administrator	Iball gocko			

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(Lewis Hall)





#### **Step 5: Adding Data Records**

Click on "Add new record" to add a new patient data entry. If you have not entered any patient data yet, your Record ID will show "No records exist yet". This is normal.

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REDCap	GECKO - Data Collection (PID 90)
<ul> <li>Logged in as weehan.gecko.test</li> <li>Log out</li> </ul>	⊞ Record Status Dashboard (all records)
<ul> <li>My Projects</li> <li>REDCap Messenger</li> <li>Contact REDCap administrator</li> </ul>	Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data
Project Home and Design	collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Complete
Project Home · E Codebook Project status: Development	Access Group, you will only be able to view records that belong to your group.
Data Collection — test	Dashboard displayed: [Default dashboard] >
Record Status Dashboard  View data collection status of all records  Add / Edit Records  Create new records or edit/view existing ones	Displaying record 0 v f 0 records 100 v records per page + Add new record Click here!
Show data collection instruments	Displaying: Instrument stars only   Lock status only   All status types
Applications	Pre- Intra- Include
se Field Comment Log	op         op         op         BDI         Histology         or           data         data         30-day         data         One-year         exclude           Record ID         fields         fields         fields         fields         fields
Help & Information	No records exist yet
Help & FAQ     Video Tutorials     Suggest a New Feature     Contact REDCap administrator	

#### Step 6: Accessing sections of the data collection form

Click on the white circle under the "Status" column on the data collection instrument to access the respective section you are trying to access.

REDCap	<b>GECKO - Data Collection</b>	PID 90	
<ul> <li>Logged in as weehan.gecko.test</li> <li>Log out</li> </ul>	Record Home Page		
<ul> <li>My Projects</li> <li>REDCap Messenger</li> <li>Contact REDCap administrator</li> </ul>	Record "12874-1" is a new Record The grid below displays the form-by entered for the currently selected re	form progress of data	nd begin entering data for it, click any gray status icon below.
Project Home and Design			Incomplete Incomplete (no data saved) ?
<ul> <li>Project Home · E Codebook</li> <li>Project status: Development</li> </ul>			<ul> <li>Unverified</li> <li>Complete</li> </ul>
Data Collection — test	NEW Record ID 12874-1		
Record Status Dashboard  View data collection status of all records  Add / Edit Records	Data Collection Instrument	Status	
Add / Edit Records     Create new records or edit/view existing ones	Pre-op data fields	Click	here!
Record ID 12874-1     Select other record	Intra-op data fields		
	30-day outcomes		
Applications	BDI data fields		
sield Comment Log	Histology data fields		
Help & Information	One-year outcomes		
Help & FAQ	Include or exclude Record	$\bigcirc$	
<ul> <li>Video Tutorials</li> <li>Suggest a New Feature</li> </ul>			
Contact REDCap administrator			





#### Step 7: Fill up the data record form

You can now fill up the data record form following the instructions shown on the form.



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#### **Step 8: Saving form progress**

If you are done with filling up the form or would like to to exit, there are multiple options of saving your progress on REDCap:

"Save and Exit Form": Clicking on this will save your progress on the form and will also exit the form, bringing you back to Records Home Page.

Click on the down arrow next to "Save and Exit Form" to access more save options such as:

"Save and Stay": Clicking on this will save your progress on the form but you will remain on the form

"Save and Go To Next Form": Clicking on this will save your progress on the form and bring you to the next section of the patient data record

"Save and Exit Record": Clicking on this will save your progress on the form and bring you to the Add/Edit Records page.







**"Save and Go to Next Record":** Clicking on this will save your progress on the form and bring you to your next patient record entry. If you do not have other patient records, it will bring you back to the Add/Edit Records page.

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"Cancel": Clicking on this will NOT save your progress on the form and will bring you back to the Records Home Page.

You can always return back to add more details should you require to do so. Please note: do not worry about the "Complete?" section, this is only for you to keep track of your own progress, we do not look at it but rather we look at what has been entered above.

* must provide value	Day on same day or		
	Sa	ve options also found here	Save & Exit Form
Days between decision to operate and surgery performed	1		Save & 🔻
* must provide value	Day 0 if same day as surge	γ	– Cancel –
Urgency of surgery Surgery urgency definitions found here @	😬 🖲 Elective 🔿 Delayı	ed O Emergency res	set
* must provide value			
Indication of surgery Surgery indication definitions found here @	<ul> <li>Biliary colic</li> <li>Acute calculous cl</li> <li>Acalculous cholec</li> <li>Chronic calculous</li> <li>Gallstone pancrea</li> <li>Common Bile Duo</li> <li>Gallbladder polyp</li> <li>Dyskinesia</li> </ul>	ystitis cholecystitis utitis tt (CBD) stone	set
Form Status			
Complete?	🕒 Incomplete 🗸	4	
Save options found here	Save & Exit Form	Save & Click dov	wn arrow to access more op
· · · · · · · · · · · · · · · · · · ·	– Cancel –	Save & Stay Save & Go To Ne Save & Exit Reco Save & Go To Ne	rd



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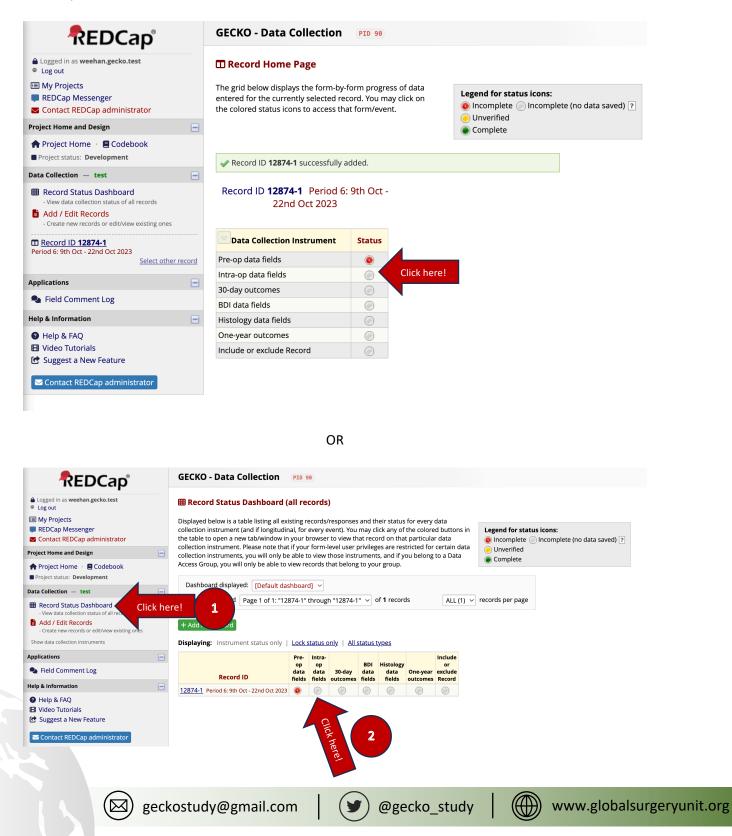




#### Step 9: Accessing other sections of the data record

Once, you save and exit the form, You can continue on to other sections. Click the button for any section you would like to access. Alternatively, you can first click on Record Status Dashboard, then click on the section you would like to access.

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## **ORIENTATING REDCAP ICONS AND SYMBOLS**

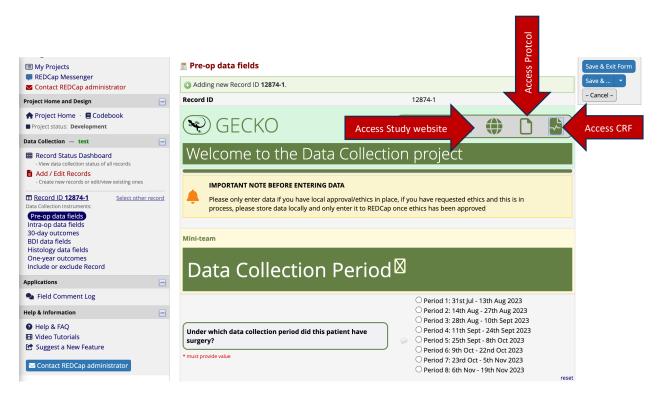
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There are multiple different symbols and options types in our form. Please read properly to familiarize youself with the different symbols and their meaning.

#### **Ethical Approvals and Data Resources**

In the Pre-op data fields, there are 3 distinct icons at the top of the form. These are data collection resources available on our form for easy access. Clicking on the Globe icon will bring you to our study website. Clicking on the white blank page will bring you to our study protcol. Clicking on the green page will bring you to our GECKO Case Report Form.

IMPORTANT: If you have requested ethics and this is in process, please store data locally and only enter it to REDCap once ethics has been approved. **Do NOT enter any data into REDCap if you have not obtained any necessary ethics approval.** If your local guidelines/ethics do not require any approval, you can continue entering data.





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#### **Radio button option**

The image below shows a section of the form with radio buttons as an option. They are options with a circle. Forms with radio buttons only allow **ONE answer** to be selected under the section.

Data Collection Period	
Radio button option Under which data collection period did this patient have surgery? * must provide value	<ul> <li>Period 1: 31st Jul - 13th Aug 2023</li> <li>Period 2: 14th Aug - 27th Aug 2023</li> <li>Period 3: 28th Aug - 10th Sept 2023</li> <li>Period 4: 11th Sept - 24th Sept 2023</li> <li>Period 5: 25th Sept - 8th Oct 2023</li> <li>Period 6: 9th Oct - 22nd Oct 2023</li> <li>Period 7: 23rd Oct - 5th Nov 2023</li> </ul>
	<ul> <li>Period 7: 2510 Oct - 511 Nov 2023</li> <li>Period 8: 6th Nov - 19th Nov 2023</li> <li>reset</li> </ul>

#### **Text box**

The image below shows a section of the form with a text box as an option. You can type in any number

into the text box as an answer.

Patient Characte	eristics
Age * must provide value	Text box option Whole years at the time of operation

#### Text box with drag-down option

The image below shows a section of the form with a text box with drag-down option. Please click on the down arrow to access the available options.

ASA grade			~
* must provide va	ASA grade descriptions fo		CIGHER
	geckostudy@gmail.com	@gecko_study	www.globalsurgeryunit.org





#### **Checklist box option**

The image below shows a section of the form with a checklist box as an option. These are options with a square instead of a circle. You can select MULTIPLE options with the checklist box.

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However, if you select "None of the above" or "None", you cannot select any other option.

	Click here!		Myocardial Infraction (MI)
			Congestive Heart Failure (CHF)
			Peripheral Vascular Disease (PVD)
			🗌 Cerebrovascular Accident (CVA) or Transient
			lschaemic Attack (TIA)
			🗌 Dementia
			Chronic Obstructive Pulmonary Disease (COPD)
			🗹 Connective Tissue Disease (CTD)
		$(\mathbf{H})$	Peptic Ulcer Disease (PUD)
Comorbidities	J	$\overline{\bigcirc}$	🗹 Hemiplegia
	Tick all that apply		🗌 Leukaemia
* must provide value			🗌 Lymphoma
* must provide value			Acquired Immunodeficiency Syndrome (AIDS)
			Diabetes Mellitus
			🗌 Solid Tumour
			Liver Disease
			🗌 Chronic Kidney Disease (CKD)
			□ None of the Above

#### **Paperclip symbols**

The image below shows a section of the form with a paperclip. Clicking on the paperclip will open a new window with more information on the required section.

Urgency of surgery	Bective O Delayed O Emergency	
	Surgery urgency definitions found here	reset
must provide value	Clar Rage	





#### **Reset button**

At the end of each segment of the form, there is a reset button. Clicking on this button will clear all selected options in the segment.

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Critical care admission	→ ○ Yes		
* must provide value		Click here! reset	

#### **Additional options**

When you click certain answer options, you may find that additional questions may appear. This is normal and not a cause of concern. Please fill up the additional questions that appear on the form.

Editing existing Record ID 12874-1. Period 6: 9th Oct - 22nd Oct 2023					
Record ID	12874-1				
Histological specimen sent for examination * must provide value	<ul> <li>9 Yes, sent for examination</li> <li>O No, not sent for examination</li> </ul>	reset		Editing existing Record ID 12874-1. Period 6: 9th Oct - 22nd Oct 2023	
- must provide value				Record ID	12874-1
Indication for sending specimen for histological examination	<ul> <li>O Routine</li> <li>O Selective</li> </ul>	reset			H O Yes, sent for examination
* must provide value				* must provide value	No, not sent for examination
Time from index cholecystectomy to histology result	Whole number  Mumber of days (0 = day of index operation)			You have completed all required questions in this form	
* must provide value			VS	Tou nave compresed an required questions in this form	
Histology result	<ul> <li>Benign</li> <li>         ○ Malignant      </li> </ul>			Form Status	
* must provide value		reset		Complete?	🕒 Incomplete 🗸
Form Status					
Complete?	B ← Incomplete ▼				Save & Exit Form Save & Go To Next Record
	Save & Exit Form Save & Go To Next Record				– Cancel –
	- Cancel -				





## **FREQUENTLY ASKED QUESTIONS (FAQ)**

#### I haven't received my REDcap username yet.

Please check your inbox and spam/junk folders first. If not received, then please contact your hospital lead to ensure they have completed the mini-team registration and inputted the correct ORCID ID and email address. Errors with these will lead to a delay in REDcap logins being issued.

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If this issue persists, please email geckoredcap@gmail.com and we will resend your account creation email. If still not received thereafter, we may need to ask you for an alternative email address to send it to.

#### Do I need an ORCID ID to participate in the study?

Each data collector, independent validator and hospital lead will require an ORCID ID to participate in the study. This is a unique indentifier which will ensure you are included correctly in authorship. Registering an ORCID ID takes only a minute. Please see the final page for more information on how to do this correctly.

#### I have forgotten my password, how can I reset it?

Email us on geckoredcap@gmail.com using the email you registered in and we will reset your password.

#### My hospital lead is not replying to my emails, what should I do?

Please email us on <u>geckostudy@gmail.com</u> and we will contact them to get in touch with yourselves.

#### I am an independent data validator, can I take part in data collection?

As a data validator, your role is to ensure the data collected by each individual is robust and valid at each site. Therefore you cannot also take part in data collection.

#### Does the data validator need to be a trainee or consultant?

Yes, this is to ensure that the data quality is high.

#### Will the independent data validator be included in authorship?

Yes, of course.









#### Can I participate in multiple periods?

Yes, absolutely.

#### When will the collaborator logins be issued?

Logins will start to be issued one week before the start of your data collection period.

#### When does the first day of follow up begin?

The day of surgery is considered to be day zero, so the first day of follow up would begin 24 hours after the operation.

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#### Do I have to complete 30 day follow up within 30 days?

No, you can collect this data after 30 days. We are interested in the events that happen within the 30 days, but the way you wish to collect this data is completely up to you. A similar case applies to one year follow up.

#### Is participating in one year follow up mandatory?

It is important to ensure the follow up for patients is complete. Note, 95% of the data collection should be complete for each record to be valid in the study.

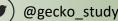
#### How should I ensure that I can follow patients up after a year?

We strongly advise to keep a record of the identifiers for the patients you have collected data for, so they can be followed up after a year. If you are unlikely to be working at the site at this time, you can provide this record to the hospital lead or supervising consultant, to ensure continuity of data collection.

#### How should I follow patients up?

It is important that you do not change your practice as a result of this study. Therefore contacting patients directly is not recommended if you would not routinely do this after 30 days or a year. Instead, it is better to review clinical records to check histology, scans, further re-admissions or other events which potentially have happened within the follow-up timeframe at 30 days and at one year.









#### What is an ORCID and how do I register?

To register on REDCap, all members are required to have an ORCID-iD. The ORCID-iD is a unique, open digital identifier that distinguishes members from every other researcher with the same or a similar name to them.

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The ID is structured as a 16-digit number (e.g. 1234-1234-1234-1234). Please ensure you have sent this identifier to your hospital lead as soon as possible (https://orcid.org/register). Some ORCID-iDs can contain an X among the 16-digits. This is normal.

Make sure you set your ORCID-iD visibility setting to "Everyone". This is done by going under profile and clicking "Account Settings"  $\rightarrow$  "Visibility"  $\rightarrow$  "Everyone". Data cannot be accessed if ORCID-iD visibility is not set to "Everyone".

ORCID Connecting research and researchers	1 Search	Wee Han Ng      English      Vee Han Ng     View my ORCID record
https://orcid.org/ 0000-0002-6037-1562 Preview public record	Account settings 2 Defaults > Email frequency	Inbox (0)      Account settings      Trusted parties      Developer tools      Logout
4	<ul> <li>Language</li> <li>Visibility</li> <li>By default, what visibility should be given to new items added to your ORCID Record?</li> <li>It Everyone (87%) users choose this)</li> <li>Trusted Organizations (5% of users choose this)</li> <li>f Only me (8% of users choose this)</li> <li>More information on visibility settings</li> </ul>	

