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# Data Entry and REDCap Database User Guide

Version 1.2

www.space-flot.com

This guide should be used in conjunction with the SPACE-FLOT study protocol.

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## 1. Pre-requisites before starting data entry

- 1.1. Basic pre-requisites
- Research office approval to conduct study
- Maintain patient confidentiality at all times
- A valid and active institutional email
- A validated, verified and password protected REDCAPS account
- Granted approval by your hospital lead to commence data entry

### 1.2. Identifying eligible patients

Eligibility criteria for inclusion into SPACE-FLOT are:

- a. All consecutive patients from January 1<sup>st</sup>, 2017 to December 31<sup>st</sup>, 2021 who are
- b. Age ≥18 years old
- c. Had gastric, adenocarcinoma and/or gastro-oesophageal cancer
- d. Had preoperative FLOT chemotherapy
- e. Had surgical resection

These patients can be identified in a number of ways. This will be institution based. These methods include:

- Surgical unit databases
- Medical oncology unit databases
- Ask your Health Information Systems/Medical Records department to run a search for the following Australian Classification for Health Intervention (ACHI) codes between the periods 01/01/2017 to 31/12/2021 inclusive

Operations	Codes	Block
Oesophagectomy	3054500, 3054501, 3055000, 3055001, 3054100, 3054101, 3053500,	858, 859,
	3053600, 3053601, 3029400	860, 861
Subtotal gastrectomy	3052300	879
Distal gastrectomy	3051800, 3051801, 3051802	875
Total gastrectomy	3052100, 3052400	879

 If none of the above apply, we suggest you speak with your Health Information Systems/Medical Records staff and inquire about generating a patient list for all oesophagectomy, subtotal, distal, and total gastrectomy performed between the periods 01/01/2017 to 31/12/2021 inclusive

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### 1.3. Setting up study ID

After generating your list of patients, create study IDs in the Patient identification log. The Patient identification log is a separate document held by the Site lead at your institution which links the Study ID, REDCap ID, and patient identifiers (e.g. UR, name, DOB). The Study ID will need to be entered into REDCap (see below), and the REDCap ID generated automatically from REDCap will need to be entered into the Patient identification log. This log will allow re-identification of patients for data entry and data cleaning purposes.

Country			Cent	ro				Study ID			
patient)											
Format	of	study	ID:	Country,	hospital	initials,	study	number	(serially	incrementing	per

Country	Centre	Study ID
Australia – ACT	Canberra Hospital	AUCH001, AUCH002, AUCH003, etc
Australia – NSW	The Royal Northshore Hospital	AURNSH001, AURNSH002, AURNSH003, etc
Australia – NSW	Bankstown/Liverpool Hospital	AUBLH001, AUBLH002, AUBLH003, etc
Australia – QL	Royal Brisbane Women's Hospital	AURBWH001, AURBWH002, AURBWH003, etc
Australia – QL	Princess Alexandra Hospital	AUPAH001, AUPAH002, AUPAH003, etc
Australia – SA	Flinders Medical Centre	AUFMC001, AUFMC002, AUFMC003, etc
Australia – SA	Lyell McEwin Hospital	AULMC001, AULMC002, AULMC003, etc
Australia – SA	Royal Adelaide Hospital	AURAH001, AURAH002, AURAH003, etc
Australia – Tas	Royal Hobart Hospital	AURHH001, AURHH002, AURHH003, etc
Australia – Tas	Launceston General Hospital	AULGH001, AULGH002, AULGH003, etc
Australia – Vic	Peter MacCallum Cancer Centre	AUPMCC001, AUPMCC002, AUPMCC003, etc
Australia – Vic	Austin Hospital	AUAH001, AUAH002, AUAH003, etc
Australia – Vic	St Vincent's Hospital	AUSV001, AUSV002, AUSV003, etc
Australia – Vic	Northern Hospital	AUNH001, AUNH002, AUNH003, etc
Australia – Vic	Box Hill Hospital	AUBHH001, AUBHH002, AUBHH003, etc
Australia – Vic	Monash Medical Centre	AUMMC001, AUMMC002, AUMMC003, etc
Australia – Vic	Western Hospital	AUWH001, AUWH002, AUWH003, etc
Australia – Vic	Bendigo Hospital	AUBH001, AUBH002, AUBH003, etc
Australia – WA	Fiona Stanley Hospital	AUFSH001, AUFSH002, AUFSH003, etc
Canada - Montreal	Montreal General Hospital	CAMGH001, CAMGH002, CAMGH003, etc
Canada - Toronto	Ontario Health	CAOH001, CAOH002, CAOH003, etc
France	Lille University Hospital	FRLUH001, FRLUH002, FRLUH003, etc
India	Christian Medical College	INCMC001, INCMC002, INCMC003, etc



Ireland	Mercy University Hospital	IRMUH001, IRMUH002, IRMUH003, etc
Ireland	St James Hospital	IRSJH001, IRSJH002, IRSJH003, etc
Malaysia	CENGILD GI Medical Center	MACMC001, MACMC002, MACMC003, etc
New Zealand	Christchurch Hospital	NZCH001, NZCH002, NZCH003, etc
New Zealand	Middlemore Hospital	NZMH001, NZMH002, NZMH003, etc
New Zealand	Dunedin Hospital	NZDH001, NZDH002, NZDH003, etc
New Zealand	Palmerston North Hospital	NZPNH001, NZPNH002, NZPNH003, etc
New Zealand	North Shore Hospital	NZNSH001, NZNSH002, NZNSH003, etc
New Zealand	Auckland City Hospital	NZACH001, NZACH002, NZACH003, etc
New Zealand	Wellington Regional Hospital	NZWRH001, NZWRH002, NZWRH003, etc
Singapore	National University Cancer Institute of Singapore	SGNUH001, SGNUH002, SGNUH003, etc
Sweden	Karolinska Comprehensive Cancer Centre	SWKCCC001, SWKCCC002, SWKCCC003, etc
The Netherlands	Erasmus University Medical Center	NEEUMMC001, NEUMMC002, NEUMMC003, etc
The Netherlands	Utrecht Medical Centre	NEUMC001, NEUMC002, NEUMC003, etc
The Netherlands	Amsterdam University Medical Center	NEAMC001, NEAMC002, NEAMC003, etc
UK	Norfolk and Norwich University Hospital	UKNNUH001, UKNNUH002, UKNNUH003, etc
UK	Queen Elizabeth Hospital	UKQEH001, UKQEH002, UKQEH003, etc
UK	Royal Victoria Infirmary	UKRVH001, UKRVH002, UKRVH003, etc
UK	Oxford University Hospital	UKOUH001, UKOUH002, UKOUH003, etc
UK	Imperial College London	UKICL001, UKICL002, UKICL003, etc
UK	University Hospitals Plymouth	UKUHP001, UKUHP002, UKUHP003, etc

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## 2. What is REDCap?

<u>REDCap</u> (Research Electronic Data Capture) is the secure web application that will be used for data capture for the SPACE-FLOT study. The SPACE-FLOT REDCap database is housed at PeterMac and has been built specifically to enable users to enter data efficiently and accurately to meet study objectives.



## 3. Accessing your REDCap account

### 3.1 Logging in to REDCap

All registered collaborators will receive an email providing access to the REDCap database for the SPACE-FLOT study.

NB: if you have not received an email or do not have access please contact <u>Kat Hall</u> (SPACE-FLOT Study Coordinator) for assistance.

3.1.1 To log in to REDCap for the first time:

Click on the email link to login for the first time



- You will be prompted to change your password
- Follow the instructions to set up a new password NB: Please keep this password secure and do not share with others.

### 3.1.2 To log in to REDCap all subsequent times:

Navigate to <u>https://redcap.petermac.org.au/</u> and enter username and password and click 'Log in'

REDCap	
Log In	
Please log in with your user name a	nd password. If you are having trouble logging in, please contact <u>Application Support</u> .
	Username:
	Password:
	Log In Forgot your password?

Sou will be directed through a two-step authentication pathway as per below



🔂 Tv	📾 Two-step verification for REDCap login								
Select You w	an option ill not be a	below to complete the second half of REDCap's two-step verification login proces ble to access REDCap until you have completed this verification step.	ss.						
0	Û	<b>Google Authenticator or Microsoft Authenticator:</b> Open the Google Authenticator or Microsoft Authenticator app on your mobile device to get the verification code associated with your REDCap user account.							
	$\searrow$	<b>Email:</b> Send an email containing your verification code to your email account. Send to david.liu2@austin.org.au							
		Cance							

Select the method you prefer to use e.g. Email, log into your registered institutional email account, wait for the automated email containing the verification code, copy and paste that code into the box below and press submit

🔒 Two-step	o verification for REDCap login	×
Select an op You will not	Enter your verification code	in process.
	Enter the verification code that you obtained from	2
° (	Email 🖌 Sent!	o get
•	Submit Cancel	
		Cancel

### 3.2 Navigating to the SPACE-FLOT REDCap Project

After you have logged in you will be taken to this page

4	REDO	îap								
	Listed below are th <u>Read nore</u> To revie	e REDCap projects to which you currently have access w which users still have access to your projects, visit t	. Click the project title to o he <u>User Access Dashboar</u>	open the <u>'d</u> .	e project	- User A - Spons	oard p Access D or Dash	ages: ashboard board (5 use	<u>rs)</u>	
	My Projects	🖕 Organize 🖿 Collapse All		Filter	project	s by title	×	B		
	Project Title			Records	Fields	Instruments	Туре	Status		
				55	105	4 forms 1 survey	۲			
				8	44	3 forms 1 survey		ø		
				3'254	137	8 forms				
<b>C</b>	SPACE FLOT			7	187	9 forms		×		
				5'585	184	6 forms				
			D	0	30	1 form		×		
				3	193	8 forms		×		
				8	36	3 forms		×		
			D	4	59	9 forms		×		

- Click on the project titled **"SPACE-FLOT"**
- This will take you to the SPACE-FLOT REDCap Project Homepage



## 4. Entering data for new cases

Every patient entered into the database will require ONE RECORD each and will have a unique REDCap identifying number. This number is automatically allocated to the record when you click "Add/Edit Records".

Data can be entered into REDCap all at once or at different points in time.

### 4.1 Creating a new record

To begin entering data, you need to create a new record.

Click "Add/Edit Records" under the "Data Collection" heading on the left-hand side of the Project Homepage



Select the green **"+ Add new record"** button.

A REDCap study ID will be automatically generated and displayed as the *Record ID*.

Total records: <b>7</b>	$\bigcirc$
Choose an existing Record ID	select record 🗸
	Add new record



This will take you to the list of data collection forms as below. Click on the radio button 'O' in the status column to begin entering data. Start at Eligibility and work your way through each data collection instrument for each patient

Data Collection Instrument	Status
Eligibility	
Baseline characteristics	$\bigcirc$
Co-morbidities (Charlson Co-morbidity Index)	
Preoperative treatment	$\bigcirc$
Surgery and postoperative care	
Complications within 30 days post-op	$\bigcirc$
Histology	
Adjuvant treatment	$\bigcirc$
Survival endpoints	

Enter in study ID. This is a unique code for this patient for the purpose of this study. The study ID should be found in the Patient Identification Log

$\leftrightarrow$ $\rightarrow$ $\mathcal{C}$ $\hat{\mathbf{e}}$ redcap.petermac.org.au/red	dcap_v12.3.3/DataEntry/index.php?pid=911&id=5&event_id	=3314&page=eligibility&auto=1	
<ul> <li>REDCap Messenger</li> <li>Contact REDCap administrator</li> </ul>	SPACE-FLOT PID 911		Save & E
Project Home and Design			- Capsel
	Actions: 📑 Modify instrument 🛛 🔁 Download PDF of in	nstrument(s) ♥ 🖼 <u>Video: Basic data entry</u>	- cancer-
Project status: Development	Eligibility		
Data Collection	Ass	ign record to a Data Access Group? select a group	$\sim$
Record Status Dashboard	Adding new Record ID 5.		
View data collection status of all records     Add ( Edit Descende	Record ID	5	
Add 7 Edit Records     - Create new records or edit/view existing ones	Study ID - allocated by your site lead	چ [	
<u>Record ID 5</u> <u>Select other record</u> Data Collection Instruments:  Eligibility	This section is to assess the eligibility of this patient		
Baseline characteristics Co-morbidities (Charlson Co-morbidity Index) Preoperative treatment	Age >=18 years old	O Yes	reset
Surgery and postoperative care Complications within 30 days post-op Histology Adjuvant treatment	Has gastric and/or gastrooesophageal cancer?	⊖ Ves ⊖ ONo	reset
Applications	Had preoperative FLOT chemotherapy?	⊖ O No	reset
Project Dashboards  Alerts & Notifications  Alerts Alerts And Alerts Al	Had surgical resection?	⊖ Yes ⊜ ⊖ No	reset
Calendar	Form Status		
Data Exports, Reports, and Stats     Data Import Tool     Data Comparison Tool	Complete?	🤉 Incomplete 🖌	
Logging     Field Comment Log		Save & Exit Form Save & 🔻	
<ul> <li>File Repository</li> <li>Data Quality</li> </ul>		- Cancel -	

Please note: You cannot enter patient identifiers into REDCap. Therefore, you must use a document titled "Patient Identification Log" to connect the patient's identifiers and the REDCap ID. This document should be captured on a secure, encrypted spreadsheet on a hospital, password protected computer.



### 4.2 Entering data into records

Work your way through each question within each data collection instrument

If there are incomplete data fields in the data collection instrument, the drop down box at the bottom of the instrument should be left as '**Incomplete'** to indicate where missing data fields require entry in the future.



Once all data fields in the instrument are entered, verify this by clicking "Complete" in the drop-down box.



### 4.2.1 Saving data

You may save the data on the form at any time by clicking the buttons at the bottom of each data collection form.



Save & Stay	Saves the record as it is and remains on form
Save & Exit Form	Saves the record and returns the user to the "Add/Edit Records" homepage
Save and Go To Next Form	Saves the form and takes the user to the <u>next form in that record</u>



Save and Go to Next Record	Saves the form and takes the user to the
	<u>next record</u>

If you save a form with incomplete data, you will be prompted that required fields are missing. You may choose from the following three options:

Okay	User is returned to the incomplete form
Ignore and leave record	User is returned to the <b>"Add/Edit Records"</b> homepage
Ignore and go to next form	User is taken to the <u>next form in the record</u>

Be sure to save your data entry at regular intervals as REDCap does <u>NOT</u> autosave.

When you return to the **"Record Home Page"** the radio button will identify which forms have been **completed**, which are still **unverified** (not all data has been entered) and which are **incomplete** using a traffic light coding system.

### SPACE FLOT (Test) PID 258

#### Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

🗹 Choose action for record 🗢

#### Record ID 2

Data Collection Instrument	Status
Eligibility	۲
Baseline characteristics	۲
Co-morbidities (Charlson Co-morbidity Index)	۲
Preoperative treatment	۲
Surgery and postoperative care	۲
Complications within 30 days post-op	۲
Histology	۲
Adjuvant treatment	۲
Survival endpoints	۲



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## 5. Entering data for pre-existing cases

You can access records at any time from the "Add/Edit Records" home page.

Using your sites <u>Patient Identification Log</u>, determine the REDCap ID that corresponds with the patients UR

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You can then select from the drop-down menu the relevant **REDCap ID** and edit the relevant form

SPACE FLOT (Test)	258		
Add / Edit Records	response by selecting it fr	om the drop-down lists below. To create a	new record
elow.	esponde by beleting it in		Ten record
NOTICE: This project is current has been moved to Production s	ently in Development stat. status.	us. Real data should NOT be entered un	til the projec
Fotal records: 7			
Choose an existing Record ID		select record 🗸	
		select record	
		2	
		3	
Data Search		4 5 6	
	All fields	7	
Choose a field to search (excludes multiple choice fields)	Air fields		
Choose a field to search (excludes multiple choice fields) Search query	Aineus		

#### Record ID 4

Data Collection Instrument	Status
Eligibility	۲
Baseline characteristics	۲
Co-morbidities (Charlson Co-morbidity Index)	۲
Preoperative treatment	۲
Surgery and postoperative care	۲
Complications within 30 days post-op	۲
Histology	۲
Adjuvant treatment	۲
Survival endpoints	۲

## 6. Data Completeness

### 6.1 Marking a form as complete

Please complete <u>all</u> fields that appear on each **REDCap record**. *NB: further information about key variables can be found in the SPACE-FLOT Protocol.* 

When a record is **complete** (i.e., all possible fields have been filled in), you can mark the form as **"Complete"** by changing the form status field from **"Incomplete"** to **"Complete"**.



This patient is eligible for this study. Please proceed with data	entry.
Form Status	
Complete?	😁 Complete 🗸
	Save & Exit Form Save & 🝷

REDCap will allow you to mark a form as complete even if all data fields are not filled. Please ensure that all your data fields are complete before marking as '**complete**'

### 6.2 Identifying missing data

As you complete each of the forms for a patient, REDCap will identify which sections are incomplete  $\bigcirc$  and which are complete  $\bigcirc$ .

### Record ID 3

Data Collection Instrument	Status
Eligibility	۲
Baseline characteristics	۲
Co-morbidities (Charlson Co-morbidity Index)	
Preoperative treatment	۲
Surgery and postoperative care	۲
Complications within 30 days post-op	۲
Histology	۲
Adjuvant treatment	۲
Survival endpoints	۲

### 6.3 Locked data

When a record is **complete** (i.e. all forms are **complete •** in the data collection table for that record), the record may be **'locked'**. This indicates to the SPACE-FLOT Data Analysis Team that the data from that patient is final and accurate.

To lock data, click **'Lock Record'** on the relevant **Data Collection** form.



## 7. FAQs

### What is the link to the REDCap database?

https://redcap.hmri.org.au Project link: https://redcap.petermac.org.au/

### How do I get a REDCap login and password?

Please provide your full name, organisational email and study site to Kat Hall (<u>katheryn.hall@petermac.org</u>).

You will then be registered for the SPACE-FLOT PeterMac REDCap database and receive an email link to enable your access.

### Who do I contact if I am having trouble accessing or using REDCap?

Please contact the SPACE-FLOT Study Coordinator, Kat Hall on <u>katheryn.hall@petermac.org</u>.

### Who do I contact if I have questions about data entry?

There will be a WhatsApp group created to support real time data collection.

Should you have any question directly related to data entry whilst entering data please post on SPACE-FLOT WhatsApp group and we will respond as quickly as possible.