

# ABMTRR Cell Therapy REDCap User Guide

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# ABMTRR Form Submission Workflow



# Accessing the ABMTRR REDCap Database

Research Electronic Data Capture - REDCap was created in 2004 at Vanderbilt University and was offered to institutions as a user-friendly web-based interface. REDCap offers an easy-to-use, and secure method of flexible yet robust data collection.

REDCap is the ABMTRR web-based application that allows centres to electronically submit the required forms for the collection of cell therapy and transplant data.

#### Access to REDCap

The ABMTRR Data Manager will create a REDCap account for required users. Once the account is setup, an automatic message will be sent to the user advising the username and asking to setup a password:

[This message was automatically generated by REDCap]

A REDCap account has been created for you in which your REDCap username is "**username**". Click the link below to set your new password and log in.

After logging in, please make sure to <u>set up your password recovery question</u>, which will allow you to use the 'Forgot your password?' link on the login page without the need to contact the REDCap Administrator. You will be prompted to set your recovery question on the My Projects page, but you can also set it on your 'My Profile' page under 'Login-related options'.

[Set your new REDCap password]

 Click the [Set your new REDCap password] link in the email you receive to set your password.



## 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.

Username:	sharks					
Password:						
Re-type password:						
Submit						

REDCap 10.1.2 - © 2020 Vanderbilt University

2. Set up a Password recovery question, when promoted. Confirm your email address is correct before saving.

Set Up Password Recovery Question	1	×
To help you easily and quickly recover need you to select a security question you have filled out this information, if you on the REDCap login screen, and it will as you will select below). In such a case, it w with your REDCap account. Setting up you wait on a REDCap administrator to reset i	your REDCap password (in case you forget i of your choice below and then provide an a u forget your password, you can click the 'Forg k you to provide a correct answer to your secu ill send a new temporary password to the ema ur password recovery question below will prev it manually if you ever forgot your password.	t in the future), we inswer for it. Once ot Your Password?' link irity question (the one il address associated ent you from having to
NOTICE: It is highly recommended that y accidentally locked out of your REDCap	you set your password recovery question now, account.	or else you might get
Select a question: - select a securit	ty question - 🗸 🗸	
Provide answer to question:	(not case sensitive)	
Please confirm your email address		
(If you attempt to recover your password, you	r new password will be sent to this email address.)	
Save Not now. Remind me aga	ain in 2 days.	
Set Up Password Recovery Question	×	
SUCCESS! You have now set up your pas	ssword recovery question.	
You will be able to easily recover your pa	issword in the future.	
Close		
REDCap <sup>®</sup> Home III My Projects + New Project @ Help & FAQ	🖼 Training Videos 🛛 Send-It 📮 Messenger	
	Login via your SVHA Username / Password. Once you have access, please contact the projects approved. or be granted access to an existing project. Welcome to REDCap!	ABMTRR Data Manager +61 2 9355 5694) to get your
	REDCap is a secure web platform for building and managing online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to virtually any data collection strategy. REDCap provides automated export procedures for seamless data downloads to	REDCap Features Build online surveys and databases quickly and securely - Create and design your project rapidly using secure web authentication from your browser. No extra software is required.
	Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.	Fast and flexible - Conception to production- level survey/database in less than one day. Export data to common data analysis
	Learn more about REDCap by watching a 🖽 <u>brief summary video (4 min)</u> . If you would like to view other quick video tutorials of REDCap in action and an overview of its features, please see the <u>Training Resources</u> page.	packages - Export your data to Microsoft Excel, PDF, SAS, Stata, R, or SPSS for analysis. Ad Hoc Reporting - Create custom queries for
	NOTCE: If you are collecting data for the purposes of human subjects research, review and approval of the project is required by your Institutional Review Board.	generating reports to view or download. e-Consent - Perform informed consent
	If you require assistance or have any questions about REDCap, please contact ABMTRR Data Manager.(+61.2.9355.5694).	electronically for participants via survey Easily manage a contact list of survey
		respondents or create a simple survey link - Build a list of email contacts, create custom email invitations, and track who responds, or you may also create a single survey link to email out or post on a website.
		Scheduling - Utilize a built-in project calendar and scheduling module for organizing your events and appointments.
		REDCap Mobile App - Collect data offline using an app on a mobile device when there is no WiFi or cellular connection, and then later sync data back to the server.
		Send files to others securely - Using 'Send-It', upload and send files to multiple recipients, including existing project documents, that are too large for email attachments or that contain sensitive data.
		Save your data collection instruments as a PDF to print - Generate a PDF version of your forms and surveys for printing to collect data offline.

## Access to REDCap Projects

The ABMTRR Data Manager will allocate the relevant REDCap project once your username has been verified. An automatic message will be sent to you advising confirmation of project access:

[This message was automatically generated by REDCap]

You have been given access to the REDCap project named "PROJECT NAME". Using your user name "username", you may log in to the project using the link below.

https://abmtrr.svha.org.au/

#### Logging into REDCap

- 1. Copy the link provided in the automatically generated email and paste into Chrome (preferred browser). Save the page to your favourites bookmark.
- 2. Log into RedCap using your username and password, set in previous steps

REDCap				
Log In				
Login via your SVHA Username / Password. C projects approved, or be granted access to ar	nce you have access, n existing project.	please cor	ntact the ABMTRR Da	ata Manager +61 2 9355 5694) to get you
Please log in with your user name and passw 9355 5694).	ord. If you are having	trouble lo	gging in, please cont	act <u>ABMTRR Data Manager (+61 2</u>
	Username:			)
	Password:			
	L	og In	Forgot your passwor	<u>d2</u>

- 3. Successful login will take you to the REDCap Home page, upon your first login
- 4. Access your projects by selecting the My Projects icon at the top of the REDCap screen

	My Projects + New Project	😮 Help & FAQ	Training Videos	Send-It	🗭 Mess	enger	Logged ir rcaldwel	as 🤅	My Profile	🕒 Log out
Login via you projects app	ır SVHA Username / Password. Or roved, or be granted access to an	nce you have acco	ess, please contact th	e ABMTRR Da	ata <mark>M</mark> anag	ger +61 .	2 9355 5694) 1	o get y	our	
Listed below users still ha	are the REDCap projects to which ve access to your projects, visit th	n you currently ha	ave access. Click the p <u>ishboard</u> .	ro <mark>je</mark> ct title to	open the	project	. <u>Read more</u> T	o revie	w which	
My Project	ts Sorganize Collaps	se All			Filter	project	s by title	×	B	
Project Title					Records	Fields	Instruments	Туре	Status	
Cell Therap	ру				2	2828	15 forms	-	×	

5. Select the project you wish to start entering data into, this will take you to the **Project Home** and Design Page

## Logging out of REDCap

1. Select the **Log out** option at the top left of the Project Home screen **OR** if you are on the REDCap Home Page, select the logout option at the top right of the screen

	REDCap	Home	🗐 My Projects	+ New Project	Help & FAQ	🖽 Training Videos	➡ Send-It	Messenger	Logged in as rcaldwell My Profile 🍽 Log out
--	--------	------	---------------	---------------	------------	-------------------	-----------	-----------	--

**Note:** REDCap will timeout after 30 minutes if there has been no activity. Logging back in will return you to the most recent page from your previous session, using the Log In button on the REDCap Auto Logout Warning screen. If you go back to the URL (favourite link) and log into REDCap from there, it will take you back to the Projects page. Please save regularly to avoid losing your data.

REDCap	Auto Logout Warning	×
×	Due to inactivity, your REDCap session has expired. Click the button below to log in again.	
	Log Ir	1

# Navigating REDCap

## **Project Home**



## Record Status Dashboard

Users will be assigned a Data Access Group (DAG), which will allow users / centres to create and view only their centre records.



\* Each record (row) represents an individual patient record

- 1. To add a new record, select the +Add New record button
- 2. To update a record, click the **AID (ABMTRR ID) number** which will open the record you have selected **AND/OR** to update a specific form, click the grey or coloured <sup>O</sup> radio button

#### 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. If you wish, you may modify the events below by navigating to the <u>Define My Events</u> page.



 $oxed{\mathscr{C}}$  Choose action for record  $\,\,\bigtriangledown\,$ 

Data Collection Instrument	Patient	+ Add new Cell Therapy Infusion:	+ Add new Cell Therapy Follow Up Infusion:	+ Add new Transplant	+ Add new Transplant FU
Patient Information					
Disease Classification	$\bigcirc$				
ALL Preinfusion					
Lymphoma Pre Infusion					
CELL THERAPY Preinfusion					
CELL THERAPY Product					
CELL THERAPY Infusion					
CELL THERAPY Follow Up			۲		
ALL Post Infusion					
Lymphoma Post Infusion			۲		
Quality Of Life Eq 5d 5l			۲		
TRANSPLANT					
HLA typing					
TRANSPLANT Follow Up					$\bigcirc$
New Malignancy					
Delete all data on event:	×				

E VIDEO: Basic data entry

#### AID (ABMTRR ID) 9 UPN: 118

Actions: 📃 Modify instrument 🔀 Download PDF of instrument(s) 空

Disease Classification	Data Access Group: [No Assignment] ?
Editing existing AID (ABMTRR ID) 9 UPN:	
Event Name: Cell Therapy	
AID (ABMTRR ID)	9
Patient identification	
UPN : 118 DOB : 01-05-1962	
DIAGNOSIS	
Date of diagnosis	🖞 🚺 🛅 Today. D-M-Y
Primary Disease for HCT / Cell Therapy	÷
DISEASE STATUS ASSESSMENT DATE Applies to diagnoses with Disease Status at Infusion assessments	
Date disease status assessed	😕 🚺 Today D-M-Y
Form Status	
Complete?	🕘 Incomplete 🗸
Lock this instrument?	
If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.	Lock
	Save & Exit Form Save &
	Cancel

## Add / Edit Records

1. To add a new record, select the **+Add New record** button

#### Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.

Total records: <b>1004</b>	
Choose an existing AID (ABMTRR ID)	select record V
(	+ Add new record

Data Search					
Choose a field to search (excludes multiple choice fields)	All fields	~			
Search query Begin typing to search the project data, then click an item in the list to navigate to that record.		]			

#### 2. To search records, type in the search query, you can search all fields or search specific fields.

#### Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.

<b>NOTICE:</b> This project is currently in Deven has been moved to Production status.	elopment status. Real data should NOT be entered until the project
Total records: 1004	
Choose an existing AID (ABMTRR ID)	- select record 🗸
	+ Add new record
Data Search	
Choose a field to search (excludes multiple choice fields)	record_id1 (AID (ABMTRR ID))
Search query Begin typing to search the project data, then click an item in the list to navigate to that record.	11 "In AID (ABMTRR ID) <b>1011</b> <i>UPN: 422</i> for event Patient
	"110" in AID (ABMTRR ID) 110 UPN: 192 for event Patient
	"1100" in AID (ABMTRR ID) 1100 UPN: 171 for event Patient
	"1101" in AID (ABMTRR ID) 1101 UPN: 172 for event Patient
	"1102" IN AID (ABMTRR ID) 1102 UPN: 173 for event Patient
	"1104" in AID (ABMTRR ID) 1104 UPN: 175 for event Patient
	"1106" in AID (ABMTRR ID) 1106 UPN: 404310 for event Patient
	"1107" in AID (ABMTRR ID) 1107 UPN: A102 for event Patient
	"1108" in AID (ABMTRR ID) 1108 UPN: 81 for event Patient
	"1109" in AID (ABMTRR ID) 1109 UPN: 83 for event Patient
	"111" in AID (ABMTRR ID) 111 UPN: 815 for event Patient

## Data Exports, Reports, and Stats

You will have access to the proforma report(s) to export data from.

Data Exports, Reports, and State	S El <u>VIDEO:</u> I	ow to use Data Exports, Reports, and Stats
+ Create New Report B My Repo	orts & Exports C Other Export Optio	ns

This module allows you to easily view reports of your data, inspect plots and descriptive statistics of your data, as well as export your data to Microsoft Excel, SAS, Stata, R, or SPSS for analysis (if you have such privileges). If you wish to export your \*entire\* data set or view it as a report, then Report A is the best and quickest way. However, if you want to view or export data from only specific instruments (or events) on the fly, then Report B is the best choice. You may also create your own custom reports below (if you have such privileges) in which you can filter the report to specific fields, records, or events using a vast array of filtering tools to make sure you get the exact data you want. Once you have created a report, you may view it as a webpage, export it out of REDCap in a specified format (Excel, SAS, Stata, SPSS, R), or view the plots and descriptive statistics for that report.

Му	My Reports & Exports								
		Report name	View/Export Options	Management Options					
	A	All data (all records and fields)	Q View Report Export Data						
	в	Selected instruments and/or events (all records)	Make custom selections						

# How to use the repeat event / form function

In some circumstances a form or event may be repeated, for a patient / record. The Cell Therapy Form Guidelines will advise when and where to use these options. If an event or form offers this function, you will see a **+Add new** above the event.

						Co repo	ollapse / u eating eve	in-collaps ent colum	e ins		
Data Collection Instrument	Patient	Cell Therapy Infusion: 30-09-2020 (#1)	Infusion: 30-06-2020 (#2)	44 + Add new Infusion: 05-11-2020 (#3)	Cell Therapy Follow Up Infusion/fu Period: 30-09-2020, 30 day (#1)	Infusion/fu Period: 30-06-2020, 30 day (#2)	Infusion/fu Period: 30-06-2020, 1 year (#3)	Infusion/fu Period: 05-11-2020, 100 day (#4)	Infusion/fu Period: 30-06-2020, 6 month (#\$)	Infusion/fu Period: 05-11-2020, 30 day (#6)	+ Add new Infusion/fu Period: 30-06-2020, 100 day (#7)
Patient Information	۲			$\smile$							
Disease Classification		۲	۲								
ALL Preinfusion		۲									
Lymphoma Pre Infusion		۲	۲								
CELL THERAPY Preinfusion		۲	۲								
CELL THERAPY Product		۲									
CELL THERAPY Infusion		۲	۲	۲							
CELL THERAPY Follow Up					۲	۲	۲	۲	۲	۲	۲
ALL Post Infusion					۲	۲					0
Lymphoma Post Infusion					۲						
Quality Of Life Eq 5d 5l					۲						
New Malignancy					۲						
Delete all data on event:	×	×	×	×	×	×	×	×	×	×	×

# Update and editing forms

#### Required fields

If required fields are missing values, and you save the form, you will receive the following message:

NOTE: Some fields are required	1!
Your data was successfully saved, by require a value. Please enter a value	ut you did not provide a value for some fields that e for the fields on this page that are listed below.
Provide a value for • Date of contact	
	Okay Ignore and leave record

Please ensure that all required fields are completed before continuing to the next form.

#### **Question Subsets**

In some questions, the forms are designed to show a subset of questions based on an answer in the previous question. For example, if you select yes – *were cytogenetic testing performed*, a subset of questions will appear.

Disease assessments at diagnosis		
Were cytogenetic testing performed	🛞 🔾 Yes 🔿 No 🔿 Unknown	reset
Disease assessments at diagnosis		
Were cytogenetic testing performed	🕛 💽 Yes 🛛 No 🔿 Unknown	reset
Tested by FISH	🔒 🔾 Yes 🔹 No	reset
Tested by karotyping	🛞 🔾 Yes 🔹 No	reset
Molecular tests were performed (eg. PCR, NGS)	🛞 🔿 Yes 🔿 No 🔿 Unknown	reset

If you reset the question – *were cytogenetic testing performed* to remove your answer you will receive a message if you have data entered in the subset of questions:

#### abmtrr-uat.svhanational.org.au says

ERASE CURRENT VALUE OF THE FIELD "amlfish" ?

The current field for which you just entered data requires that the field named "amlfish" be hidden from view. However, that field already has a value, so its value might need to be reset back to a blank value.

Click OK to HIDE this field and ERASE its current value. Click CANCEL if you DO NOT wish to hide this field or erase its current value.



By clicking OK, it will reset all the subset questions.

## Help Text

Questions that require further explanation will have help text associated with it. Hover over the to reveal the text.

Seizure	😃 💽 Yes 🔿 No 🔿 Unknown 🔗 reset
Seizure type	
Severity	
Hemiparesis/paraparesis/other motor deficit	Grade 3 - Any clinical seizure focal or     generalized that resolves rapidly: or Non-
Cerebral oedema	convulsive seizures on EEG that resolve with intervention. Grade 4 - Life-
Hallucinations	threatening prolonged seizure (>5 min); or Repetitive clinical or electrical seizures without return to baseline in between)
Tremors	Yes No Unknown reset

## Auto Fill in dropdown lists

For large dropdown list questions, these fields have an auto fill function as you start typing key words. Start typing in the word and it will display options from the dropdown list that you can choose from.

v1.0 - Released N	ovember 2020				
				Data Access Gr	oup: [No Assignment] ?
🥔 Editing existin	g AID (ABMTRR ID) 1 UPN: 85				
Event Name:	atient				
AID (ABMTRR ID)				1 To marke the record, see the record act record Home Page	ion top-down at top of the
Current Hospital * must provide value			F	br Brisbane Private	
Demographics				Mater Brisbane	
Patient UPN		Surname ID	4 characters	Mater Private Brisbane Royal Brisbane	acters emaining
Date of birth	D-M-Y				
Sex	O Male O Female				

## Field History / Field log comments

Each question / field has a history and comment log associated with it. Click on the H to view the data history of the field:

tient identification		
PN : 85 OB : 10-01-1950		
AGNOSIS		
ate of diagnosis		0.4.Y
rimary Disease for HCT / Co	ellular Therap	View data history
COTE LYMPHOBLASTI	LEOKAEM	
LL classification	LEUKAEM	B-lymphoblastic leukemia / lymphoma with
	LEUKAEM	🖉 🛛 B-lymphoblastic leukemia / lymphoma with
LL classification	e "dc_prim_di	B-lymphoblastic leukemia / lymphoma with
LL classification Data History for variable Listed below is the history of esults are sorted from earlie	e "dc_prim_di: all data entere est to most rec	B-lymphoblastic leukemia / lymphoma with     for record "1"     x ed for the variable "dc.prim_dis" for AID (ABMTRR ID) "1". The data history enc.
LL classification Data History for variable Listed below is the history of esults are sorted from earlie Date/Time of Change	e "dc_prim_dia all data entere est to most rec User	s" for record "1" s" for record "1" s" for the variable "dc, prim_dis" for AID (ABMTRR ID) "1". The data history en. Data Changes Made
LL classification Data History for variable Listed below is the history of sulta are sorted from earli Date/Time of Change 03/11/2020 03:37:18	e "dc_prim_dia all data entere est to most rec User rcaldwell	B-lymphoblastic leukemia / lymphoma with     Gor record "1"     A for record "1"     Cort de variable "dc.prim_dis" for AID (ABMTRR ID) "1". The data history ent.     Data Changes Made     Acute myelogenous leukaemia (10)
LL classification Data History for variable Listed below is the history of esults are sorted from earlie Date/Time of Change 03/11/2020 03:37:18 06/11/2020 03:58:10 06/11/2020 03:58:10	e "dc_prim_dia i all data entere est to most rec User rcaldwell rcaldwell	B-lymphoblastic leukemia / lymphoma with     Gor record "1"     X     Gor record "1"     X     Gor the variable "dc.prim_dis" for AID (ABMTRR ID) "1". The data history enc.     Data Changes Made     Acute myelogenous leukaemia (10)     Acute lymphoblastic leukaemia (20)

# Click the comment logo ito enter in comments:

#### Sield Comment Log

**ALL classification** 

This pop-up displays all the field comments for the record and field specified below. Users with access to data entry forms may leave one or more comments on any field on a data collection instrument, after which the balloon icon will stay lit up to signify that comments exist for that field for this record. All field comments for all records/fields can also be viewed, keyword searched, and filtered on the <u>Field Comment Log</u> page in this project. NOTE: If you wish to prevent all users in this project from editing or deleting field comments below, see the Additional Customizations popup on the Project Setup page.

B-lymphoblastic leukemia / lymphoma with ł 🗸

×

#### AID (ABMTRR ID): <u>1</u> Event: **Cell Therapy**

Field: dc\_prim\_dis ("Primary Disease for HCT / Cellular Therapy")

Date/Time	User	Comments
11/11/2020 10:18pm	rcaldwell	Field updated as per new correspondence
		Comment Cancel

The comment icon will now show as yellow, to signify that comments are added to the field.

Primary Disease for HCT / Cellular Therapy	🙁 😝 🖌 Acute lymphoblastic leukaemia	~

You can view all field comments in a project by accessing the Field Comment Log

#### Field Comment Log

This page displays the Field Comment Log for all records/events/fields in this project. You may use the controls below to perform keyword searches in the comments as well as filter the comments by record, event, field, or data access group. Keep in mind that if you do not have user privileges to view some data collection instruments, then comments for any fields on those instruments will not be displayed in the table. Also, if you belong to a data access group, then you will only see results for records that belong to your group. The entire Field Comment Log is downloadable as a file in Excel/CSV format.

Field Comment L	.og Filters:	Il records V for All events	Export entire log		
Results returned	1: 1 /	All fields  All users  All data access groups  Keyword search  Search tips			
Click button to view comment log	Record	Field	Comments		
🤪 1 comment	<u>1 (#1)</u> UPN: 85 Cell Therapy	dc_prim_dis (Primary Disease for HCT / Cellular Therapy)	rcaldwell (11/11/2020 10:19pm): "Field updated as per new corresp	oondence"	

## **ABMTRR Cell Therapy Form Guidelines**

For assistance in completing the cell therapy forms, follow the <u>ABMTRR Cell Therapy Form Guidelines</u>

# For Further Help

Website:<a href="https://www.abmtrr.org/index.php/resources/data-management/">https://www.abmtrr.org/index.php/resources/data-management/</a>Email:abmtrr@svha.org.au

# References

PA Harris, R Taylor, R Thielke, J Payne, N Gonzalez, JG. Conde, Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.

PA Harris, R Taylor, BL Minor, V Elliott, M Fernandez, L O'Neal, L McLeod, G Delacqua, F Delacqua, J Kirby, SN Duda, REDCap Consortium, The REDCap consortium: Building an international community of software partners, J Biomed Inform. 2019 May 9 [doi: 10.1016/j.jbi.2019.103208]