

UoR REDCap Service Guide

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What is REDCap?

REDCap (Research Electronic Data Capture) is a secure web-based application for building and managing online databases and surveys. It is suitable for use in participant-based research, such as clinical trials, observational studies, longitudinal studies, and survey-based projects. It provides sophisticated functionality for the management of data collection in research, and a safe environment for the processing of personal and confidential information.

Using REDCap, project teams can build electronic data collection instruments quickly and easily. Research data can be collected from participants by means of surveys or entered directly by members of a project, from anywhere with an internet connection. The REDCap mobile app allows offline data capture. REDCap supports the whole data lifecycle, including data collection, validation and analysis. System logging provides an audit trail of all actions including data changes. Data can be exported in CSV format, XML, and to common statistical packages (Stata, SPSS, SAS, R), facilitating analysis and long-term archiving on project completion.

UoR REDCap is managed by the Research Engagement Team in the Library and hosted in accordance with institutional <u>Information Compliance Policies</u>. Users and projects are subject to approval. All users are required to comply with the <u>UoR REDCap Terms of Use</u>.

How can REDCap be used?

REDCap can be used for non-commercial research and research-related projects which have a designated PI who is a member of UoR staff. Non-commercial research funded by commercial organisations is permitted, and REDCap may be used for multi-centre studies where there is a project PI or Co-I based at the University. REDCap cannot be used to provide services (either gratis or for a fee) to a third party, e.g. to support external research teams where there is no University staff member involved in the study.

Who can use REDCap?

Members of University staff, students, and persons external to UoR who are working on a project with a UoR PI or Co-I may obtain REDCap user accounts. Students and non-UoR users must be authorised by a Sponsor, who must be a permanent academic member of staff with a REDCap account. Students will be sponsored by their supervisor or tutor. External users will be sponsored by the UoR PI or Co-I. All users must accept the UoR REDCap Terms of Use (Appendix 1) in order to be granted access to REDCap.

University academic staff and students are eligible to create their own REDCap projects. Projects (excepting practice projects) must be authorised by a PI. For REDCap purposes, the PI is the UoR project PI, the UoR Co-I in a collaboration, or a student's supervisor or tutor.

Is REDCap right for my project?

REDCap is research database first and a survey tool second. Data capture can be via data entry form as well as survey; multiple instruments can be linked together; a scheduling module enables longitudinal data collection; validation functions and event logging support data quality and integrity; and advanced features are available, such as an API that can be used to interact programmatically with other services. REDCap also provides a secure collaborative environment that allows flexible configuration of users' permissions to view, edit and export data.

REDCap is designed to be a secure environment, suitable for the management of identifiable information under institutional oversight. For this reason user accounts and projects must be requested and approved, and approval is required to move a project from development to production (i.e. into live data collection mode).

If you only require a survey tool, and your requirements are not complex, other solutions may be more suitable, such as Jisc Online Surveys or Microsoft Forms. Find out more about online survey tools available through the University.

How do I get a REDCap user account?

To obtain a user account, a <u>REDCap User Account Request</u> must be submitted. Requests will be processed within 2 working days wherever possible, although completion of the request may depend on the promptness of responses from a Sponsor.

How do I apply for a REDCap project?

In order to create a project, a <u>REDCap Project Request</u> must be submitted. Requests will be processed within 2 working days wherever possible, although completion of the request may may depend on the promptness of responses from a PI.

Is there a cost to use REDCap?

There is no cost to use REDCap. Eligible users may create REDCap projects free of charge.

REDCap is funded for five years from 2020. In the interest of maintaining a sustainable service beyond the funded period, we will introduce charges for external grant-funded projects from 1st August 2022.

Where can I find REDCap and get help?

Visit the <u>UoR REDCap web page</u> to apply for a user account, apply for a project, and access UoR REDCap. Here you can download the UoR REDCap Service Guide and 'Data management in REDCap: a good practice guide'.

If you have any enquiries, or want to find out whether REDCap would be suitable for your project, contact the UoR REDCap Administrators at uor-redcap@reading.ac.uk.

How is REDCap managed?

UoR REDCap is managed by Robert Darby, Research Data Manager, based in the Research Engagement team in the Library. Administrative support is provided by Rogan Dixon (Senior Library Assistant, Research Engagement) and James Church (Assistant Research Development Manager). Enquiries and support requests should be addressed to uor-redcap@reading.ac.uk.

REDCap hosting and systems administration is undertaken by DTS.

Can I try REDCap out?

If you are a member of the University, once you have a user account, you can create a practice project at any time. This will enable you to familiarise yourself with the application and its capabilities, and to test functionality. Practice projects require no authorisation, but may not be used for real data collection.

When setting up a practice project you should include the word PRACTICE in the project title, and for Purpose of the project you should select 'Practice / Just for fun'. Practice projects can be maintained in development status only. Any request to move a practice project into production will be rejected. Practice projects can be maintained as long as you hold a UoR REDCap user account.

Can REDCap be used to store identifiable information?

REDCap can be used to store and process identifiable information (i.e. personal data as defined under data protection laws). Participant identifiers stored in REDCap may include direct identifiers such as names and email addresses, and indirect identifiers, such as pseudonymous key codes and data which when combined with other information (wherever it may be stored) are sufficient to identify an individual. Some features of REDCap, such as the survey invitation and e-consent functions, necessarily involve the processing of direct identifiers.

The project owner is responsible for ensuring the fair and lawful processing of personal data associated with a project. Projects should collect the minimum amount of identifiable information required. Where there is no detriment to the project, data should be processed in REDCap without direct identifiers, i.e. by designating participant records using pseudonymous key codes and avoiding the collection of unnecessary direct or indirect identifiers, such as name, email address, postcode, date of birth, etc.

The project owner should grant project members permission to view and export identifiable information only where this is required for the purposes of the project. User rights can be modified to prevent access to specified data instruments (e.g. a demographics instrument containing participant identifiers) and to allow export of deidentified data only. See Appendix 2 for a detailed specification of available user rights.

Because REDCap may be used in research that involves the processing of sensitive personal information, the <u>UoR REDCap Terms of Use</u> include a number of data protection-related requirements, including:

- members of UoR staff must have completed UoR mandatory online <u>Data</u>
 <u>Protection and Information Security training</u> within 2 years previous to applying for a user account;
- all users must have read and understood the following UoR <u>Information</u>
 <u>Compliance Polices</u>: the University's Data Protection, Information Security, Bring Your Own Device, Remote Working and Information Security Incident Response Policies;
- all users must have read and understood the UoR <u>Data Protection for</u> <u>Researchers</u> guide.

<u>Data management in REDCap: a good practice guide</u>, which can be downloaded from the UoR REDCap web page, contains guidelines for processing data collected from research participants.

Do REDCap projects need ethical approval?

Ethical approval is required for research projects; projects created for purposes other than research (e.g. for operational support, impact assessment, etc.) do not need ethical approval. **All research projects** must be approved by a Research Ethics Committee (either a School or the University REC); project owners will be required to provide Administrators with details of ethical approval before the project can be moved to production. Practice projects and draft projects do not require ethical approval – but may not be used to collect real data. You can set up and start designing a project while your ethical approval is pending.

How can I learn how to use REDCap?

REDCap the Basics (download from the UoR REDCap web page) provides an overview of REDCap features. For a comprehensive, detailed guide to REDCap functions and workflows, download the Vanderbilt Meharry REDCap User Guide. Bear in mind that some of the workflows, e.g. for gaining access to REDCap and creating projects, will be different in UoR REDCap, and that not all of the features described in the guide are enabled in the UoR service.

Within REDCap itself you will find Help and FAQs, <u>training videos</u> and on-screen guidance. The REDCap Consortium also provides access to a <u>Shared Library</u> of data collection instruments and forms that can be downloaded and used.

UoR REDCap users can join the <u>UoR REDCap Community of Practice Team</u> to connect with other REDCap users in the University and share knowledge and skills. We also use the Team to share service communications, e.g. about software updates and training. You will be asked if you wish to join the Community of Practice when you request a user account. You can also contact us at any time to ask to join the Community of Practice.

What if I want REDCap to do something it doesn't do?

If there is something you want REDCap to be able to do, and you cannot find the required functionality in REDCap or in any of the helps or user guides, a further option is to explore the Repository of External Modules. This is a repository of curated external modules that can be downloaded and installed by a REDCap administrator. External modules are add-on packages of software that can extend REDCap's current functionality, and provide customisations and enhancements for REDCap's behaviour and appearance, at either system or project level. The modules have been created and submitted by software developers at various REDCap institutions around the world.

Anyone may search the repository for available modules, but modules can only be installed by a REDCap administrator. If you see a module you would like to be installed, you can send a request to the UoR REDCap Administrators.

Is there any training available?

A course 'UoR REDCap: a secure web application for managing data collection in participant-based research' is offered to research students on a termly basis through the Reading Researcher Development Programme.

How do I set up a project?

A <u>REDCap Project Request</u> must be submitted for every REDCap project that will involve the collection of real data (practice projects are exempt from this requirement). Projects (excepting practice projects) must be authorised by a PI. For REDCap purposes, the PI is the UoR project PI, the UoR Co-I in a collaboration, or a student's supervisor or tutor.

Following approval of a new project request, a blank slate project will be created by an Administrator. The project will have the survey feature enabled, and comes with three user roles having predefined user rights. These roles are:

- PI/Study Manager: high-level user rights, including to create and copy projects, to
 design and set up projects, to modify project user rights, to view and edit all data,
 to create and rename records, and to export all data including identifiers;
- Data Collector: rights to view and edit data (these may vary between instruments, e.g. to restrict access to identifiable information), to create and rename records, and to export only de-identified data;
- Data Analyst/Statistician: rights to read only data (these may vary between instruments, e.g. to restrict access to identifiable information), and to export only de-identified data.

A description of user rights and full specification of these roles is provided in Appendix 2.

The project owner will be assigned to the PI/Study Manager role. If the project owner is a student, the project PI will also be added to the project in the PI/Study Manager role, so that they can review the project design and authorise moving it to production.

Users added to a project can be assigned to any one of the three user roles provided, or a project owner can create their own user roles, or define customised user rights for each user.

User rights should be granted with caution, as permissions to view and export identifiable information carry risks relating to participant confidentiality and data protection, while permissions to edit and delete records may affect data integrity.

If the project owner wishes to add users to a project who do not already have a REDCap account, they should be asked to submit a <u>REDCap User Account Request</u>. The project owner will be notified when the new user account has been set up and the user can be added to the project.

A project is created in development status. In this mode the instruments are designed and tested. When the project is ready for data collection, it must be moved to production status. This can only be done by a REDCap Administrator.

From the Project Setup tab on the Project Home page the project owner can submit a request to move the project to production. If it is a research project, the Administrator will check that details of ethical approval by a Research Ethics Committee have been provided: if ethical approval was pending at the time of the original Project Request, the project owner will need to provide the relevant details to the REDCap Administrators.

Student projects will additionally require authorisation to begin data collection by the project PI (your tutor or supervisor). The PI must be added to the project as a user, so that they are able to review it before it is made live and request any design changes. Requests to move projects to production will receive a response within one working day.

As a University user you can create or copy projects at any time for practice or drafting purposes. These projects **can only be maintained in development status**, i.e. they cannot be used for live data collection, unless a Project Request has been submitted and approved. If a request is made to move a project to production for which a Project Request has not previously been submitted, this will be rejected. If you intend to begin setting up a project for live data collection, you are advised to **submit a Project Request before you start drafting the project**.

What if I need to amend a project once it has gone live?

You should ensure your project is thoroughly tested before live data collection commences, to minimise the need to make any changes to projects during data collection. If the need to make changes to a project does arise while it is in production status, it is recommended that these changes be tested by creating a copy of the project.

A copy of a project can be created from the Other Functionality tab on the Project Home page. The project should be named with the original project name and the words: TEST COPY. In the Project settings section on the Project Setup page, you should set the Purpose of the project to 'Practice / Just for fun'. Copy projects may be maintained in development status only, and will not be authorised to be moved into production.

Once required design changes have been finalised, the changes should be drafted in the original project and submitted for review. Minor design changes to projects in production will be automatically implemented. But if the changes would cause critical issues, for example if they would result in the loss of data, these will be forwarded to an Administrator for approval. The project owner will be responsible for any data loss caused by making design changes to a project in production.

What happens at the end of a project?

REDCap is not intended for use as project archive. When a project is completed, the project owner should export the project data to an appropriate storage location (e.g. on the University network or a University member's OneDrive account). The project dataset can be downloaded in CSV format, in full or de-identified form, and a full project backup can be exported as a single XML file (CDISC ODM format), allowing the whole project to be re-imported into any REDCap instance in the future.

In accordance with the requirements of the University's Research Data Management Policy, on completion of a research project, an anonymised, fully documented dataset should be deposited in a suitable data repository for long-term preservation. This dataset should be made available wherever possible on publication of project findings. The dataset should be openly accessible where no reason to restrict access exists, or available on a restricted-access basis where commercial, legal or ethical reasons for restriction apply. Guidance on the preservation and sharing of research data is provided on the research data management website.

Projects that have been inactive in REDCap for one year will be deleted by the Administrators. The project owner will be given notice so that data can be exported before the project is removed.

If a project is held on REDCap for a period of time after the project has been completed, its status should be changed from Production to Analysis/Cleanup or Completed as required (this can be done from the Project Home on the Other Functionality tab). In Analysis/Cleanup status active data collection functionality is disabled, and records can be locked. In Completed status, the project can no longer be accessed by any members of the project, and must be returned to accessible status by an Administrator.

What if the project owner leaves the University?

If a project owner leaves the University while a project is held on REDCap, it must be deleted from REDCap or transferred in REDCap to another PI/Study Manager.

Description for funding applications

REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data collection and management for participant-based research studies. UoR REDCap (https://www.reading.ac.uk/research-services/research-data-

management/managing-your-data/uor-redcap) is hosted by the University's Digital Technology Services in accordance with institutional Information Compliance Policies (https://www.reading.ac.uk/imps/information-compliance-policies). Access is via encrypted SSL website with multi-factor user authentication. REDCap provides fine-grained control over user rights, allowing management of permissions to create projects and to add, view, edit and export data. UoR REDCap service users and projects are subject to University approval. Identifiable information can be stored in UoR REDCap in accordance with University policies. The final dataset can be de-identified and exported for long-term storage and sharing.

Version	Date	Author	Comments
1.0	16/09/2020	Robert Darby	First Version

Appendix 1. UoR REDCap Terms of Use

In using the University of Reading (UoR) REDCap service you agree:

- to use REDCap in accordance with the <u>REDCap License Terms</u>, for noncommercial research, educational or operational projects which have a designated UoR PI/project lead only, or for practice purposes using dummy data only, and not to use REDCap as the basis for providing a service (either gratis or for a fee) to any third party;
- if you are a member of UoR staff: that you have completed UoR mandatory online <u>Data Protection and Information Security training</u> within the two years previous to requesting a UoR REDCap user account;
- that you have read and understood the following UoR <u>Information Compliance</u>
 <u>Polices</u>: the University's Data Protection, Information Security, Bring Your Own
 Device, Remote Working and Information Security Incident Response Policies;
- that you have read and understood the UoR <u>Data Protection for Researchers</u> guide;
- to process any identifiable data stored in REDCap in accordance with the requirements of the Data Protection Act;
- to use your access credentials to access REDCap only as long as you remain a member of a REDCap project;
- not to share your REDCap access credentials with anyone, and to change your password immediately if you suspect it may have been compromised;
- if you suffer, or suspect that you may have suffered, a data security compromise, to report the incident without delay to the owners of all projects which you have access to and to the REDCap Administrators, and if required to report an <u>Information Security Incident</u> in accordance with University procedure;
- if you are the Sponsor of a student or non-UoR user of UoR REDCap, to be responsible for the sponsored user's awareness of and compliance with the UoR REDCap Terms of Use.

Additionally, if you are the PI or the owner of a REDCap project you agree:

- to use REDCap only for non-commercial research, educational or operational purposes in accordance with the <u>REDCap License Terms</u>;
- to ensure that any research project has obtained all necessary ethical approvals by the date it is moved to production;
- to ensure that all members of the project team working on the direction or under the auspices of the University, including UoR staff, students, and non-UoR team members, are suitably trained in data protection, have read the UoR <u>Data</u> <u>Protection for Researchers</u> guide, and will act in compliance with all data protection laws while working on the project;
- to use REDCap for the processing of participant identifiable data only where necessary for the purposes of the project;
- to use the data stored in REDCap only for the purpose for which it was collected, and in accordance with the information given to/consent given by the participant;

- to immediately remove from your REDCap project any user who ceases to be a
 member of the project team and to inform the REDCap Administrator (<u>uor-redcap@reading.ac.uk</u>) when a user no longer requires access to REDCap for
 purposes of the project;
- to accept responsibility for any data loss caused by moving a project to production or making any design changes to a project in production;
- to be responsible for all project data that have been collected under your management as long as they continue to be stored in REDCap;
- to keep any personal data stored in REDCap under review, and to remove them from REDCap when the purpose(s) for which they were collected no longer apply;
- if you leave the University, to delete the project from REDCap or transfer it in REDCap to another PI/project owner;
- when the project is completed, to delete it from REDCap or to change the project status in REDCap to Completed, in which status it can be maintained for a period of up to one year, and on the expiry of which term the project must either be returned to production or deleted from REDCap.



Appendix 2. User rights and user roles

This table lists the user rights which can be edited by the project owner, and the default rights granted to the three user roles available in the standard project template (PI/Study Manager, Data Collector and Data Analyst/Statistician). The PI/Study Manager role will be assigned to the project owner when the Administrator sets up the project. The PI/Study Manager can modify the rights of other users on a project, and can modify the default user roles and create new user roles. Rights should be granted with caution, as permissions to view and export identifiable information carry risks relating to participant confidentiality and data protection, while permissions to edit and delete records may affect data integrity.

Note: when the project is created, the Administrator will also grant the project owner permission to create or copy projects, so that a copy of the project can be created if necessary to test design changes once it is in production. This permission is a universal user attribute, granted by modifying the REDCap user profile, and is not a user right specific to a project.

USER RIGHT	NOTES	PI/STUDY MANAGER	DATA COLLECTOR	DATA ANALYST/ STATISTICIAN
Data Entry Rights	Grants user "No Access", "Read Only", "View & Edit", "Edit Survey Responses" rights to the project's data collection instruments. These can be used to control access to instruments containing identifiable information. Data entry rights can be specified for each instrument in a project. No Access should be used for users who do not require access to instruments containing identifiable information, e.g. demographics and consent instruments. Note that data entry rights only pertain to a user's ability to view or edit data on the web page; data export rights are set separately in Data Exports.	View & Edit	View & Edit	Read Only
Expiration date	Automatically terminates project access for the user on date entered. Will be set by the Administrator based on information provided by the PI/Study Manager in the User Request form. No date will be set for the PI/Study Manager as they will be responsible for data stored in REDCap after project completion.	No date	As per User Request form	As per User Request form

USER RIGHT	NOTES	PI/STUDY MANAGER	DATA COLLECTOR	DATA ANALYST/ STATISTICIAN
Project Design and Setup	Grants user access to add, update or delete any forms within the project. Also allows the user to enable and disable project features and modules. High-level privilege, which should be restricted.	Yes	No	No
User Rights	Grants user access to change the rights and privileges of all users on a particular project, including themselves. Any user with these rights can change the rights of other users on a project, e.g. giving them the ability to view and export identifiable information, and edit and delete data. High-level privilege, which should be restricted to the PI/Study Manager only.	Yes	No	No
Data Access Groups	Grants user access to create and add users to Data Access Groups. For multisite studies this allows the ability to place barriers between sites' data (i.e. group A cannot see, export, or edit group B's data). Users with this privilege can see all project data regardless of group. High-level privilege, which should be restricted.	Yes	No	No
Data Exports	Grants user "No Access", "De-identified Only", "Remove all tagged Identifier fields" and "Full Data Set" access to export all or selected data fields to one of the 5 default programs in REDCap (SAS, SPSS, R, Stata, Excel). Default Access: De-Identified. "De-identified Only" access shifts all dates even if they are not marked as identifiers. Non-validated text fields and note fields (free text) are also automatically removed from export. "Remove all tagged Identifier fields" ONLY removes fields marked as identifiers and does NOT automatically remove non-validated text fields or field notes and does NOT date shift. In reports and in the API data exports, any fields that have been tagged as "Identifier" fields will be removed from the export file. In the PDF exports, it will include the Identifier field but it will be indicated with text [*DATA REMOVED*]. Data export rights are not linked to data entry rights, which must be separately configured.	Full Data Set	De-identified Only	De-identified Only
Add/Edit Reports	Grants user access to build reports within the project. If user does not have access to a data collection instrument that the report is pulling data from, those fields will not appear in the report.	Yes	Yes	Yes
Stats & Charts	Grants user access to view simple statistics on each field in the project in real time. If user does not have access to a data collection instrument, that instrument will not be listed on the page.	Yes	Yes	Yes

USER RIGHT	NOTES	PI/STUDY MANAGER	DATA COLLECTOR	DATA ANALYST/ STATISTICIAN
Survey Distribution Tools	Grants user access to manage the public survey URLs, participant contact lists, and survey invitation log. Email addresses (i.e. identifiable information) may be listed for the participant contact lists and invitation logs. Emails can be downloaded to a device.	Yes	Yes	No
Calendar	Grants user access to track study progress and allows user to update calendar events, e.g. mark milestones, enter ad hoc meetings. Identifiable information can be entered and viewed in the "notes" field, and exported in PDF.	Yes	Yes	Yes
Data Import Tool	Grants user access to download and modify import templates for uploading data directly into the project bypassing data entry forms. This gives the user the capability to overwrite existing data and should be used with caution.	Yes	No	No
Data Comparison Tool	Grants user access to see two selected records side by side for comparison. This can be helpful when using double data entry. Data can be printed and downloaded to a device. Identifiable information can be viewed. ALL data discrepancies for all fields in project are displayed and can be downloaded to user with access to this module – NOT linked to Data Entry Rights or Data Export Tool Rights.	Yes	Yes	No
Logging	Grants user access to view log of all occurrences of data exports, design changes, record creation, updating & deletion, user creation, record locking, and page views. This is the audit trail for the project. Data including identifiable information can be viewed and downloaded.	Yes	No	No
File Repository	Grants user access to upload, view, and retrieve project files and documents (e.g. protocols, instructions). In addition, it stores all data and syntax files when data is exported using the Data Export Tool. While users with restricted data export rights will not be able to access saved identified exports, they will be able to view any other sensitive information stored in the file repository such as photos or scanned documents.	Yes	Yes	Yes
Data Quality	Grants user access to find data discrepancies or errors in project data by allowing user to create & edit rules; and execute data quality rules. If user does not have access to a data collection instrument that the query is referencing, access will be denied for query results.	Yes	Yes	Yes
Create Records	Grants user access to add records and data to database.	Yes	Yes	No

USER RIGHT	NOTES	PI/STUDY MANAGER	DATA COLLECTOR	DATA ANALYST/ STATISTICIAN
Rename Records	Grants user access to change key ID of record. This right should only be granted to trained staff, as it can cause problems with data integrity	Yes	No	No
Delete Records	Grants user access to remove an entire record. Records deleted are records lost. Few, if any, team members should have this right.	No	No	No
Record Locking Customization	Grants user access to customize record locking text. Will only be applicable to users with Lock/Unlock rights. Sometimes used for regulatory projects to provide "meaning" to the locking action.	Yes	No	No
Lock/Unlock Records	Grants user access to lock/unlock a record from editing. Users without this right will not be able to edit a locked record. User will need "Read Only" or "View & Edit" to lock/unlock a data collection instrument.	Yes	No	No