

REDCap – Terms of Use

Medical Data Integration Center (MeDIC) Cologne

1. REDCap Project Setting

- User accounts can be requested by employees of the University Hospital Cologne (UKK) and external project partners.
- Only organisational/business email accounts can be used to request REDCap access. The use of private accounts is prohibited.
- Users can request access as **REDCap Project Manager** (REDCap PM) or **REDCap User**. Each project requires two REDCap PMs, which are employed at the UKK and take over specific responsibilities within the project (see Section 2).

2. Responsibilities of REDCap Project Managers (REDCap PMs)

2.1. Design of new REDCap projects

- REDCap PMs can request new projects via the submission of a signed [request form](#) to transferstelle-medic@uni-koeln.de.
- REDCap PMs are responsible for the design of the required data collection instruments in a **REDCap Test Instance**.
- REDCap PMs are solely responsible to make sure that no patient data is stored in the Test Instance.
- Before moving a REDCap project into productive mode, the REDCap PMs need to request the transfer of their project to a **REDCap Production Instance** via email to transferstelle-medic@uni-koeln.de.
- The MeDIC REDCap Admin will move the REDCap project to the productive instance and provide new login details to the REDCap PMs and their users so that patient data can be entered.

2.2. Management of REDCap User Rights:

- REDCap PMs are responsible for user management within their REDCap project. This includes:
 - **Training** of the REDCap Users.
 - Addition and removal of user **access to the REDCap project**.
 - Management of **access rights to specific data collection instruments** (no access, read-only access, full edit access).
 - Management of permitted **record operations** (create, rename and delete records).
 - Information of the MeDIC REDCap Admin in case a user account is no longer required within 4 weeks.



3. Data Governance

- MeDIC REDCap Instances can only be used for research and more specifically non-commercial observational studies. The use for clinical care, clinical trials or other types of interventional studies is prohibited.
- Only pseudonymized patient data can be stored in the Production REDCap Instances.
- All REDCap PMs and REDCap Users are responsible for using the REDCap according to the terms of use defined by the MeDIC – UKK and must use REDCap according to the applicable ethical and data protection regulations of the University Hospital Cologne.

4. User support

- The REDCap PMs are the first contact point in case of questions regarding the REDCap project or technical difficulties.
- If the REDCap PMs are not able to assist the REDCap User, a request can be submitted to the MeDIC REDCap Admin (medic-support@uni-koeln.de)
- MeDIC will respond to the request within 5 working days.
- Service times: 09:00 – 17:00 Mo – Fr, no bank holidays of NRW

5. The following actions are prohibited

- It is forbidden to use the REDCap instance for any purpose that is not covered by the license agreement (“non-commercial research purposes only”)
- It is forbidden to use REDCap in any way that violates applicable national or EU data protection laws and regulations.
- It is forbidden to take any action that violates the REDCap Instance and its security.
- It is forbidden to store any patient data in the REDCap Test Instances.
- It is forbidden to share any login details.
- It is forbidden to use private email addresses to request user accounts.

6. MeDIC rights

- MeDIC reserves the right to not grant access to the PM or users, if the access forms are not correctly entered or submitted.
- MeDIC reserves the right to remove access to the REDCap Instances upon any actions listed in section 5.
- MeDIC reserves the right to monitor the following user activity
 - Login, logout.
 - Activities performed by the user and the time of their execution.
 - Any access to or changes in records.
 - Monitoring of online status.
- MeDIC reserves the right to monitor the content of the REDCap database.
- MeDIC reserves the right to suspend the access for the user, if the he/she has not logged in the project for more than 6 months. In this case, REDCap PMs need to request the reactivation of the user account.

7. Maintenance

- MeDIC reserves the right to schedule a maintenance window (0.5 – 1 day) on a monthly base if required.
- The maintenance window will be scheduled during office hours between 09:00-17:00 Mo – Fr and announced via email one week in advance.
- Urgent security updates will be announced one day before.
- Daily backups are scheduled during night.
- For data recovery, only the whole project can be recovered, and only the REDCap PMs are allowed to issue data recovery requests. Data is set back to requested day of backup. Changes after backup are lost.

8. Publications

- All publications related to the REDCap software itself - including those describing its methodology, functionality, or capabilities in supporting electronic data capture for research - must be forwarded to MeDIC prior to publication.