

# ADDITIONAL TERMS AND CONDITIONS

Version 1.0, 21 November 2025

regarding DKF Services for the Application “Data Management System REDCap” (DMS REDCap)

IMPORTANT – PLEASE READ CAREFULLY: BY USING DKF SERVICES FOR THE APPLICATION DMS REDCap YOU AGREE TO BE BOUND BY THESE ADDITIONAL TERMS AND CONDITIONS AND BY THE GENERAL TERMS AND CONDITIONS OF DKF. IF YOU ARE AN AGENT OR EMPLOYEE OF THE INTENDED USER, YOU INDIVIDUALLY REPRESENT AND WARRANT TO DKF THAT YOU ARE AUTHORIZED TO BIND THAT PARTY TO THIS ATC. IF YOU DO NOT AGREE TO THIS ATC, THEN YOU ARE NOT AUTHORIZED TO RECEIVE THE SERVICE.

These are the ADDITIONAL TERMS AND CONDITIONS (“ATC”) for the Application “Data Management System REDCap” (DMS REDCap) and related services, agreed between the University Hospital Basel, Department of Clinical Research, Switzerland (“DKF”) and your company or research group (“Client”).

## 1. Scope of ATC

These ATC shall apply to contracts entered into by DKF with Clients where these ATC are referenced, e.g. on the subject of providing DMS REDCap, services related to DMS REDCap, and services related to installations of DMS REDCap managed under the responsibility of the Client. Deviating, contrasting or supplementary terms and conditions of the Client shall not apply and shall be deemed as not incorporated into the contract, unless their application is agreed to explicitly and in writing.

## 2. Defined Terms and References

- 2.1 “Service” means all agreed tasks that DKF is performing or intends to perform for Client under an executed contract.
- 2.2 “Client” means receiver of Services.
- 2.3 “DKF” means “Departement Klinische Forschung”, provider of Services.
- 2.4 “Effective Date” means the date of the last Party signing the Contract
- 2.5 “Application” is the digital Data Management System REDCap (DMS REDCap) provided to the Client that includes certain functionalities as further disclosed to the Client. For instance, the Application can be used to establish electronic case report forms for clinical studies (eCRFs) or data collection tools for surveys. Within the Application, various types of documents and records, such as patient data, technical data, uploaded documents, etc., can be managed. The Application is hosted at the domain dkfbasel.ch by DKF and includes all modifications, customizations,

enhancements, revisions, updates, upgrades, and documentation that are required to keep the Application constantly functional as required for its purpose.

- 2.6 “Controller” means the entity which determines the purposes and means of the processing of data as defined in the applicable Data Protection Laws and Regulations.
- 2.7 “Data Protection Laws and Regulations” means all applicable human research and data protection laws and regulations (in the currently valid version).
- 2.8 “Contract” means the document signed by both parties setting forth costs incurred to the Client for provision, setup, operation, update, and maintenance of the Application as well as consulting services related to the Application.
- 2.9 “Processor” means the entity which processes data on behalf of the Controller as defined in the applicable Data Protection Laws and Regulations.
- 2.10 “User” refers to each employee, consultant, client, or other agent of Client who accesses the Application on Client’s behalf or invitation.
- 2.11 “DKF REDCap License Agreement” refers to the Non-Profit End-User License Agreement between the University of Basel, Department of Clinical Research (Participant ID 8254) and Vanderbilt University, Center for Technology Transfer and Commercialization, 1207 17th Avenue South, Suite 105, Nashville, Tennessee 37212, USA.

### **3. Property and Licensing**

#### **3.1 License**

Subject to this ATC, DKF hereby grants to Client

- a) a non-exclusive, revocable, non-sublicensable, non-transferable, right to access and use the Application under the terms of the DKF REDCap License Agreement solely for its internal and non-commercial business operations.
- b) a non-transferable right to use any and all work products resulting from consulting services related to the Application provided hereunder solely for its internal business operations.

Client is solely responsible for providing all telecommunications, hardware and other equipment necessary for accessing the Application. DKF retains the right, in its sole discretion and upon three day’s prior written notice to Client, to restrict or terminate access to the Application by Client and/or particular Users if Client and/or its Users make use of the Application in a way that violates any applicable federal, state, local or international laws or regulations, or if DKF reasonably believes it necessary to preserve the security, integrity or accessibility of the Application or the DKF network, or if Client breaches the terms of the DKF REDCap License Agreement.

#### **3.2 Ownership**

DKF reserves all rights not expressly granted to Client in this ATC. Client acknowledges and agrees that, except as specifically set forth in this ATC or in Contract, Client accesses and uses the Application respecting the terms of the DKF REDCap License Agreement.

### 3.3 Restrictions on Use

Except otherwise specifically permitted under this ATC, Client shall not, nor will Client permit any third party to (i) copy, modify, distribute, sell, assign, pledge, sublicense, lease, loan, time-share, rent, outsource, deliver, or otherwise transfer the Application or any of its components to any third party in whole or in part, provided that Client may copy DKF documentation as needed for use by its Users; (ii) derive or attempt to derive or discover the source code of any portion of the Application by any means; (iii) reverse engineer, decompile, disassemble, or translate the Application or any part thereof; (iv) upload, post, mail, publish, transmit or distribute in any way the Application or its components. Client may not access the Application for purposes of monitoring its availability, performance or functionality, or for any other benchmarking or competitive purpose, except as specifically agreed upon by the parties.

### 3.4 No Trademark License

No license, right or interest in the trademarks, trade names or service mark of either party or its licensor is granted hereunder, except as either party may agree in writing.

## 4. Additional Terms

### 4.1 Support

DKF shall use commercially reasonable efforts to correct errors (a material failure of the Application to function in accordance with its documentation and functionalities) or provide a reasonable workaround. Client shall provide access, information, and support to assist DKF in the process of resolving any error. This is Client's sole and exclusive remedy for errors.

### 4.2 Security

The Service Level Terms and Conditions sets out commercially reasonable measures to ensure that the security of the Application meets the functionalities and the required state of the art. Client is responsible for the security of all User names and passwords granted to it, for the security of the systems used to access the Application and for its Users' compliance with this ATC. Equally, Client is obliged to keep User names and passwords confidential.

### 4.3 Sensitive Information

Client acknowledges that the Application is not intended for processing of health information, credit card numbers, financial account numbers, or other similarly sensitive personal data unless coded or anonymized by state-of-the-art methods, and express authorization from the competent regulatory authorities has been obtained. Client assumes all risk arising from use of any such sensitive information with the Application, including the risk of any inadvertent disclosure or unauthorized access thereto.

#### 4.4 Processing of Personal Data

In its role as Controller and while using the Application, Client shall process personal data in accordance with the requirements of relevant Data Protection Laws and Regulations. Client shall in such event have the sole responsibility for the accuracy, quality, integrity, and legality of personal data at all stages of its processing and the means by which Client acquired personal data.

If DKF is considered to be a personal data Processor to Client, DKF shall fulfill its obligations as a Processor in accordance with relevant Data Protection Laws and Regulations.

#### 4.5 Disclaimer of Warranty

The Application, access thereto, and any services provided hereunder are provided on an “as is” basis, and DKF: (a) does not make, and hereby expressly disclaim, any and all warranties, representations or conditions, whether express, implied, statutory or otherwise, including but not limited to warranties of merchantability, fitness for a particular purpose, and any warranties arising from course of dealing, usage, or trade practice; (b) does not warrant that access to the Application will be uninterrupted, error-free, or secure, or that any information, software, or other material accessible through the Application is free of viruses (although DKF represents that it will use commercially reasonable efforts to avoid viruses and other harmful contents or components); (c) shall in no event be liable to Client or anyone else for any inaccuracy, error or omission in, or loss, injury or damage (including loss of data) caused in whole or in part by, or failures, delays or interruptions of the Application.

### 5. Service Level Terms and Conditions

#### 5.1 Definition of Availability

Provided that Client remains current in its payment obligations to DKF, Client shall have the right to and DKF shall have the obligation to perform the availability provisions set forth herein.

“Availability” or “Available” means Client is able to log in to the Application. “Unavailable” or “Unavailability” means Client is unable to log in to the Application, subject to the following subsections.

#### 5.2 Scheduled Downtime

The Application may be inaccessible to Client during scheduled downtime, which will be notified to Client in writing or online on the access login portal of the Application sufficiently in advance. Scheduled downtime may occur for less than four (4) hours. Scheduled downtime shall not be considered times when the Application is unavailable.

#### 5.3 Exceptions to “Unavailability”

In addition to scheduled downtime, any period in which Client is unable to use the Application due to the conduct of Client or any circumstances outside of the control of DKF or its third party providers, including but not limited to the following, shall not be considered times when the

Application is Unavailable: (i) A failure or malfunction resulting from scripts, data, applications, equipment, or services provided and/or performed by Client; (ii) Outages initiated by DKF or its third party providers at the request or direction of Client for maintenance, back up, or other purposes; (iii) Outages occurring as a result of any actions or omissions taken by DKF or its third party providers at the request or direction of Client; (iv) Outages resulting from Client's equipment and/or third party equipment not within the sole control of DKF; (v) Events resulting from an interruption or shut down of the Application due to circumstances reasonably believed by DKF to be a significant threat to the normal operation of the Application, the facility from which the Application is provided, or access to or integrity of Client content (e.g., a hacker or a virus attack); (vi) Outages due to system administration, commands, file transfers performed by Client representatives; (vii) Other activities Client directs, denial of service attacks, natural disasters, changes resulting from government, political, or other regulatory actions or court orders, strikes or labor disputes, acts of civil disobedience, acts of war, and other force majeure items; (viii) Client's negligent or deliberate breach of its material obligations as set out in this ATC; (ix) Lack of availability or untimely response time of Client to respond to incidents that require its participation for source identification and/or resolution.

#### 5.4 Target System Availability

The "Target System Availability Level" is the Application availability level that DKF plans to meet or exceed during each calendar quarter. The Target System Availability Level is 99% in any calendar quarter. The "Application Availability Level" is the number of hours during a particular period that the Application was Available to Client, excluding scheduled downtime (as defined above), divided by the total number of hours during such period (as measured at the end of such period).

#### 5.5 Management of Application

Client acknowledges that

- (a) DKF does not recommend using the Application for projects exceeding the limit of 15'000 records.
- (b) DKF does not recommend using the Application for projects exceeding the limit of 5'000 fields.
- (c) it is the Client's responsibility to validate projects and their functionalities when migrating projects from another system or from another REDCap installation (i.e. functionality loss while importing projects, e.g. via xml files).
- (d) DKF takes no responsibility for performance issues of projects and reserves the right to close or remove a project if it blocks the system or services.
- (e) DKF - apart from a requested and agreed review before the first deployment - does not review projects for any further deployments, if not specifically requested before the 'change to production' request comes in.
- (f) Client is responsible for ensuring that the project specific functionalities (e.g. branching logics, calculations) are still working correctly after a software update.
- (g) Projects may only be hosted on the Application if the Client is a member of the University of Basel or of the University Hospital Basel or one of its affiliated institutions. If Client changes the institution, Client is requested to prove continued affiliation with one of above-mentioned institutions or find a successor or move the projects.
- (h) Client is responsible for ensuring that documents uploaded in projects are coded (if not approved differently by the ethics committee) and have a maximum file size of 20 MB.
- (i) Client will inform DKF in case a REDCap super user changes or leaves

(j) Client is responsible for all data presented in their project's public REDCap report and dashboard section.

(k) If Client requests availability of additional external REDCap modules on the Application then Client will bear the costs of initial validation and installation of such modules incurred by DKF. DKF may reject installation of additional external REDCap modules if the Application might risk failure or malfunction or if the external module represents a security risk.

(l) Should Client request and DKF provide services for Client related to the Client's installations of REDCap that do not fall under the terms of the DKF REDCap License Agreement, then DKF will only provide services allowed under the terms of the Client's own REDCap Non-Profit End-User License Agreement.

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