## **REDCap and REDCap Survey end-user agreement**

Research Electronic Data Capture (REDCap) and REDCap Survey (further collectively referred to as REDCap) are electronic data capture tools provided by the Clinical Research and Evidence-Based Medicine Unit within the Second Medical Department of the Aristotle University Thessaloniki (AUTh), Thessaloniki, Greece represented by its department head Dr. Apostolos Tsapas, Professor in Internal Medicine. REDCap was created by Vanderbilt University and is hosted by the AUTh Information and Technology Center servers. REDCap is accessible via an encrypted connection at <a href="https://redcap.med.auth.gr">https://redcap.med.auth.gr</a>. Use of the REDCap infrastructure is subject to the general policy of the AUTh Information and Technology Center, which is available at <a href="http://www.it.auth.gr">http://www.it.auth.gr</a>.

Today on \_\_/ \_\_/ \_\_\_ in Thessaloniki, Greece the following parties:

a) Clinical Research and Evidence-Based Medicine Unit which can be reached at <u>cebm@auth.gr</u> and is further referred to as the REDCap administrator

and

b) \_\_\_\_\_ (surname), \_\_\_\_\_ (name) who can be reached at \_\_\_\_\_\_ @auth.gr and is further referred to as the end-user or the user,

have mutually agreed as follows:

1. The user is actively affiliated with Aristotle University Thessaloniki (university stuff, student) and owns an institutional user account (in the form of <u>user@auth.gr</u>). As such the user shall be granted access to the REDCap platform which will only be used to support the research program of the user and the user's supervisor. The user shall receive a personal e-mail at the above mentioned address with the login credentials. The user shall not share the login credentials with any other university stuff or any other third party personnel working on the project. In case the user suspects any unauthorized use of the login credentials, the REDCap administrator shall be notified immediately.

2. For the specific purpose of the research project the user might request that additional university and/or other third party personnel are granted access to the REDCap platform and the user's research project. Relevant contact details and personal e-mail addresses are to be communicated to the REDCap administrator who is responsible for issuing relevant login credentials. Again, login credentials

are strictly personal and shall not be shared anyhow. Users granted access to the REDCap servers are to abide by the terms of the current agreement and the general policy of the AUTh Information and Technology Center.

3. For research involving human subjects it is the absolute responsibility of the user to seek and obtain approval by the appropriate institutional review board(s) and/or ethics committee(s) per local legislation before the project is moved to production and data collection can commence. While the project is still in draft mode, only mock data may be collected for testing purposes and actual data collection is not allowed at the development stage. A copy of the protocol as well as relevant approval letters shall be provided to the REDCap administrator in order to move project to production. Of note, the REDCap administrator is not responsible to and cannot verify protocol approval status. The user is responsible to notify the REDCap administrator immediately for any amendment to study approval status imposed by regulatory authorities.

4. For research involving human subjects only de-identified data might be collected by the user and stored in REDCap. It is the absolute responsibility of the user to obtain written informed consent and maintain anonymity of the research subjects. The REDCap administrator cannot be held accountable for any violation of the participants' anonymity.

5. Prudent use of the REDCap survey feature is encouraged and use for advertising purposes is strictly forbidden. The user is responsible to abide by local legislation regarding unsolicited bulk mailing.

6. The REDCap administrator will put every effort to make sure that access to the platform is uninterrupted. The REDCap administrator and the AUTh Information and Technology Center have also measures in place (such as backup and firewall services) to assure the integrity of the data collected in REDCap database. Nevertheless, the user understands that he/she is the owner of the data collected in REDCap database and therefore the user is solely responsible for their integrity. The REDCap administrator cannot be held accountable for any loss or unauthorized exposure of the user's data. The REDCap administrator cannot also be held accountable for service interruption or security breach.

7. The user understands that the research project will be actively maintained in REDCap per the timeframe agreed by the two parties prior to study initiation. The REDCap project will be archived after this time. Once archived, the data will remain in the database (unless requested by the user to be deleted permanently).

The study might be reopened upon user request following approval of the REDCap administrator.

8. The REDCap administrator will make effort to provide guidance and technical assistance to the end-user regarding project functionality if requested. Nevertheless, the user understands that resources of the REDCap administrator are very limited and provision of technical support cannot be guaranteed. For that reason the user is encouraged to consult the online manual and training material prepared by the REDCap consortium before referring to the REDCap administrator. By all means, advice is provided on a voluntary basis and the user is solely responsible for good project functionality.

9. The REDCap administrator reserves the right to temporarily withhold access to certain user(s) and/or project(s) at any time and without prior notice for security reasons. The REDCap administrator also reserves the right to permanently suspend certain user(s) and/or project(s) or even terminate the service and permanently delete data stored in the REDCap database. In that case the user shall be notified in due course in order to obtain any data collected up to that point in the REDCap database.

10. Any publications resulting from the user of REDCap to collect and manage data should include the following REDCap citation:

Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009;42(2):377-81

This contract shall be signed by the two parties in two (2) prototypes in English.

For the first party

For the second party

Apostolos Tsapas Professor in Internal Medicine -----