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**NJH REDCap Governance**

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# Introduction

## LicenseThis document covers the REDCap license “National Jewish Health” issued by Vanderbilt and signed by Gregory Downey, MD, EVP.

## Background

REDCap (Research Electronic Data Capture) is a mature, secure web application for building and managing online surveys and databases. It is a useful, free alternative to Microsoft Excel, Access, or commercial survey tools. The main goal for REDCap is to deliver a tool that is built for researchers without the need for dedicated programmer(s).

## Strategic goals/aims

Research Informatics Services strives to provide secure and stable access to REDCap to the institution.

## Overall governance

Day-to-day governance is the responsibility of the REDCap administrator. Strategic decisions (e.g., capacity upgrades, consult pricing, training needs) are made by the Research Informatics Advisory Committee (RIAC) in consultation with appropriate subject matter experts. Marketing and communication matters are being handled by the Director of Research Informatics Services and the REDCap administrator.

# Stakeholders

We have identified a number of stakeholders for the NJH REDCap program.

## Main Stakeholders

 **NJH Research and Clinical Staff Members**
REDCap is an important resource provided by NJH to both research and clinical staff members. NJH therefore has a vested interest in keeping REDCap secure and stable while continuing to grow its user base.

**IST**
The Information Services and Technology (IST) provides server resources and technical expertise necessary for maintenance and upgrades of the system.

**RIAC**

The Research Informatics Advisory Committee provides oversight for strategic decisions and helps disseminate information about REDCap to their respective areas.

##

## Users

We have a number of different types of users. All users must complete NJH REDCap online training.

* **Internal**
Internal users are NJH employees or affiliates that have an NJH network login. These users are authenticated via LDAP to the Active Directory domain. After completing training, the user’s NJH network username is added to the REDCap User Whitelist. This allows internal users to use their NJH network username and password to log in to REDCap. When a user is removed from the NJH Active Directory, they will also no longer be able to access REDCap. Below are some examples of internal REDCap users:
	+ **Principal Investigators (PI)**PI’s usually have an oversight role in REDCap. They monitor the project over time, but often leave day-to-day operations to other users.
	+ **Research Coordinators (RC)**RC users demand the most support time on average. They are usually tasked to design, run and maintain one or more REDCap projects.
	+ **Clinical Staff**This user group is similar to the RC user group in support time, but usually works on Quality Control/Improvement projects.
* **External**
	+ External users are outside, non-NJH persons that require access to project(s) within the NJH REDCap instance. All external users require an NJH sponsor, which is an NJH employee and usually the person who created the project the external user needs to access. All external users must complete online REDCap training and are not allowed to copy/create projects in REDCap, nor do they receive emails from the REDCap administrator about trainings, upgrades, etc. An external user’s account is added to REDCap through table-based authentication and is set to expire one year after it’s created. That date can be pushed out up to one year at a time if the NJH sponsor indicates to the REDCap administrator that the external user is still active.
	+ **Joint Operating Agreement (JOA) Employees**

Employees of institutions with which NJH has signed a JOA will be allowed the same access to REDCap as an external user. One person at the JOA institution will be designated as the “sponsor” for all other users at their institution who complete REDCap training and gain access to NJH REDCap. The sponsor will have the capability to create/copy new projects in REDCap and will add JOA users to these projects. The sponsor must notify the REDCap administrator when a JOA user should no longer have access to NJH REDCap. The sponsor and project users are responsible for all compliance necessary for their own institution, including privacy and IRB.

* **Participants/subjects**The only interaction this user group has with REDCap is through survey functionality. Their questions are usually directed to the REDCap project owners for a particular survey.

## REDCap Consortium

The consortium consists of all REDCap administrators and the development team at Vanderbilt University. The consortium is a good source of information regarding problems, issues, new features, and all other REDCap related matters. The NJH REDCap administrator is actively involved in the consortium.

## Institutional Review Board (IRB)

The IRB has a vested interest in keeping REDCap secure. To support HIPAA compliance, the REDCap servers are regularly monitored by the NJH IST department.

# Hardware Governance

## Change Management

All changes to the NJH REDCap system hardware and/or software follow the established change management policy and procedure developed by IST. This process is required to minimize risk and impact to the organization and to comply with regulatory requirements.

## Upgrades

Any upgrades to the hardware that runs REDCap are discussed between the NJH IST team and the REDCap administrator. The goal is to minimize impact for all users.

## Uptime

NJH strives to keep REDCap operational 24/7 except for scheduled maintenance. Upgrades to the main production server are scheduled for every fourth Thursday of the month after 6pm Mountain Time and announced on the main REDCap web page. This time frame has proven to have the least impact on our users.

The exception to this rule is when a zero-day security issue surfaces (e.g. heart bleed) or other security related critical hardware firmware updates are required. Because these issues could potentially impact personal health information, we try to patch such serious issues as quickly as possible, but typically at night when user activity is low.

## Infrastructure

The infrastructure the NJH REDCap instances run on are being maintained by the NJH systems administration IST team. The instances are hosted in the NJH data center located at the main campus. A once daily server snapshot is performed at 00:00 and twice daily database backups are performed at 00:05 and 12:05 to safe-guard against data loss. A systems monitoring plan has been established for both the development and production servers to ensure consistent availability of REDCap for users. The NJH IST team and the REDCap Administrator work closely together to deal with any issue regarding the REDCap server.

## Security

Physical security is safe-guarded by hosting REDCap in a secure data center. All client connections using the REDCap service to the server are being encrypted automatically.

Only individuals with an NJH network user ID can have a REDCap account on the NJH REDCap instance. Individuals without an NJH network user ID can request an external REDCap user ID from the REDCap administrator, but have to prove that they have a connection with an existing user (i.e. they must be sponsored by an NJH employee or a JOA designee). All external REDCap user accounts are set to expire one year after they are created. That date can be pushed out up to one year at a time if the NJH sponsor indicates the external user is still active.

REDCap itself provides the mechanism necessary to keep sensitive data secure. In order for a user to gain access to any project, they will need to be added to that project and assigned user rights appropriate for them. The user rights assignment is a responsibility of the project creator and anyone else they’ve designated to add users to the project. Inactive users are automatically suspended after six months of inactivity. The REDCap administrator can also manually suspend or un-suspend any user within the REDCap system as necessary and monitors termination emails generated by IST from the NJH Oz HR System for necessary suspensions. No user is deleted to maintain integrity of the internal log files for IRB oversight purposes.

# Software Governance

## REDCap Instances

NJH currently maintains three different REDCap installations under the “National Jewish Health” license issued by Vanderbilt and signed by Gregory Downey, MD, EVP:

**Main Production (Prod)**The bulk of REDCap users utilize this installation. Upgrades are carefully planned and announced to all users on the main REDCap web page.

**Non-Production Environment (Test)**This instance is used to test out new versions, plugins and any other items that require testing before rolling it out to the main production server.

**Non-Production Environment (Dev)**This instance is used to test out new operating systems and any other items that require more extensive testing before rolling it out to the Test non-production server.

## Upgrades

Upgrades to REDCap need to strike a balance between uptime and making new functionality and pertinent bug fixes available.

Vanderbilt tends to release new REDCap LTS (long term support) versions every six months. It is the policy of the REDCap Administrator to not upgrade to a newer version immediately, but to adopt a wait and see approach to account for any new bugs introduced by new features. This enables our users to have the latest features relatively soon, while at the same time safe-guarding stability as much as possible. The DEV instance is upgraded as soon as possible to the latest version in order to test out new features.

This policy has led to average upgrade cycles of roughly every six months, but several months after the latest LTS version has been released. Non-branch upgrades that only include bug fixes are implemented monthly. This causes our users to have access to the newest feature relatively quickly while minimizing risks from bugs or other programming errors.

The monthly upgrades are done first with our TEST server (usually the 2nd Friday of the month). The REDCap administrator runs scripts on the TEST server to test basic functionality of REDCap and exploratory testing of any new features. An upgrade of the PROD server (to match the TEST version) usually occurs the 4th Thursday of the month.

The REDCap Consortium Regulation and Software Validation Committee creates validation scripts that can be used by individual sites. They are usually several versions behind as Vanderbilt releases new versions quite frequently. We believe it is more important to install the latest security fixes, so upgrade as necessary before the final validation is complete on the Vanderbilt REDCap side.

We do not provide a 21 CFR Part 11, HIPAA validated version and will only address that if the need arises.

## Extensions (Hooks, plugins, custom code)

Any extensions that need to be installed on the REDCap server will need to be approved by the REDCap administrator. A member of the Research Informatics Services team will test and double check the source code for any extension on the development instance before enabling the extension on the main production instance.

## API

Any user is free to use the REDCap API to link to outside systems. API documentation is available within REDCap. Users are responsible for their data once it leaves the NJH REDCap servers. API token users need to be approved by the REDCap Administrator after agreeing to the API Token terms of use.

# Services

Research Informatics Services provides a number of different services and types of support regarding REDCap.

## Training

Full User Training is required to gain access to the REDCap application and is completed online.

We provide additional individualized or personalized training sessions or demos as needed. Please see the Academic Affairs price list for more information.

## Consults

We provide consulting services at a nominal hourly rate. Please see the Academic Affairs price list. These consults are meant to get users up and running with their project. We conduct a one- to two-hour free intake consultation before beginning to charge, which usually results in an estimate.

Work only starts after the estimate has been approved and appropriate billing information has been provided.

The most common types of consults are:

* Translating standard case report forms into REDCap forms quickly
* Migrating existing datasets (usually in Excel or Access) to REDCap
* General study design (setting up Branching Logic, Survey Queues & Invitations, Longitudinal Design)
* Providing study design advice
* Building scoring tools (e.g., various versions of FACT, FIM, MRS)
* Building adverse event trackers using standard terminology

## User support

We provide basic REDCap access and support to all users at no charge. Support is limited to matters related to the NJH REDCap instance. Part of this support is the approval of new project creation and production changes approval. The change approval process is meant to safeguard against any potential data loss.

# Marketing

Promotion is achieved through the following means:

## Spyderweb and the Clinical Research Resources websites

The Clinical Research Resources website can be accessed through a button on Spyderweb and includes the following information about REDCap:

* Training links and information
* Frequently Asked Questions
* Consulting services

## REDCap Flyer

A one-page overview of all NJH REDCap-related services has been developed and is distributed at NJH-related events.

# REDCap Consortium

NJH strives to increase its profile in the REDCap global community by actively engaging other community members in the weekly conference calls and the yearly REDCap conference.

## Weekly conference calls

The REDCap Administrator usually attends the weekly conference calls on Friday in order to keep up to date of all the latest developments coming out of Vanderbilt.

## REDCap conference

NJH tries to send at least one participant to the yearly REDCap conference organized by Vanderbilt and tries to actively participate in one or more events.

## Day to day interaction

The REDCap Administrator tries to be actively involved on the REDCap administrators’ community group that is governed by Vanderbilt. This involves reading all the posts, replying when appropriate and writing posts detailing new innovation or highlighting new issues with the NJH REDCap installation.

# Intellectual Property Governance

## General REDCap license

Vanderbilt does require consortium partners to sign a license agreement for use of REDCap. More details can be found at <http://project-redcap.org/> under the “Become a Partner” tab.

## Custom work

Consultation activities usually yield products that might be useful for other parties. NJH makes these products available upon request as long as appropriate credit is given.

**Templates**The REDCap administrator has the ability to transform any project into a template that can be accessed by all other NJH REDCap users. The prospective project template must be adaptable to other situations and have no personal health information. It must also not be available as a form in the global shared library. Elevation to template status is at the discretion of the REDCap administrator.

**Data Dictionaries**Almost all consultations yield some form of data dictionary. Entire data dictionaries or parts of the data dictionary (e.g., scoring tools, standardized surveys) can be reused by the REDCap Administrator or by users upon request.

**Innovation**

Any innovation stemming from the efforts of NJH staff members regarding REDCap is property of NJH and can be made available to the general public provided that the appropriate credit is given.

## Papers

Any publications stemming from the innovative efforts of NJH staff regarding REDCap is property of NJH and should cite the appropriate grant numbers.

# Compliance

NJH strives to be compliant with the appropriate laws and regulations regarding REDCap. However, most laws and regulations have a human component and NJH expects REDCap users to follow these guidelines and not rely solely on REDCap for compliance. For more details about compliance, contact NJH compliance staff.

## HIPAA

The NJH REDCap main production instance supports HIPAA compliance. Various IRBs are satisfied with the REDCap security measures and allow the capture of personal health information within the NJH REDCap instance.

## Security

NJH strives for the highest level of security for REDCap. New security vulnerabilities (e.g., Heart Bleed) are to be patched as soon as the appropriate patch becomes available.

## Publications

Researchers using REDCap are required to cite REDCap as described below:

*Study data were collected and managed using REDCap electronic data capture tools hosted at National Jewish Health.REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing:*

* an intuitive interface for validated data entry
* audit trails for tracking data manipulation and export procedures
* automated export procedures for seamless data downloads to common statistical packages
* procedures for importing data from external sources*1*

1Paul 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 Apr;42(2):377-81.

# Organizational Governance

The ultimate responsibility for the NJH REDCap instances lies with the NJH Executive Vice President of Academic Affairs and the NJH principal investigators.

## Resources

* **FTE**
The NJH REDCap instances are currently supported by 0.75 FTE (REDCap Administrator and Developer). There is no dedicated portion of the NJH system administrator budget allocated to REDCap specifically. System administrator support falls under the normal NJH IT systems support.
* **Allocation**Roughly 60% of the REDCap Administrator’s time is dedicated to regular user support (Issues, Approvals). The other 40% is dedicated to other task such as training, demos, and consultancy.

## Decision process

There are a number of different decision levels for the current REDCap instances.

* **Low Impact**These are the day-to-day decision handled mostly by the REDCap administrator and the system administrator. The decisions mostly deal with when to upgrade an instance and its subsequent parts (e.g., Apache, Red Hat). It might also cover turning various features on or off depending on the situation.
* **Medium Impact**To ensure stakeholder integration in matters related REDCap, any decisions of greater impact will be brought before the Research Informatics Advisory Committee. The Committee meets the first Friday of every month.
* **High Impact**Any decisions related to REDCap that have a high impact should be made by NJH leadership.

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