

# Resource – Frequently Asked Questions (FAQs)

# **Compliance**

#### Is REDCap HIPAA-compliant?

REDCap is definitely capable of compliance with just about any standard – for example, HIPAA, 21CFR Part11, and FISMA standards (low, moderate, or high). Each of those standards has been used across various consortium sites, as well as other standards (including similar international regulations, like GDPR).

REDCap is server software. Be mindful that no software alone is truly compliant with any standard. It is the environment into which software is installed that can be called compliant.

The 'environment' includes the policies and procedures of the individual institutions, management teams, and REDCap project study team(s), touching on all aspects of how and where the data is stored. So 'compliance' involves how the software is installed, maintained, and supported — such things as what server settings are used by your institution, how servers are tested and maintained, how often data is backed up, how passwords are controlled, how the REDCap project teams manages the actual study, etc. Those decisions 1) do not singularly involve (nor get singularly defined by) REDCap itself, and 2) are entirely up to every REDCap partner institution to determine.

If a system has the survey feature enabled, the default way survey webpages are displayed does comply with ADA Section 508. Project design may affect, or entirely negate, that default compliance though.

#### Is REDCap 21CFR Part11 Compliant?

The appropriate version of this question is, can a REDCap project at Atrium-Wake be Part11 compliant? Within the Atrium-Wake Enterprise, REDCap has the potential to be 21CFR Part11 compliant. To maintain a project in REDCap under this compliance standard, users must follow a more strict and detailed data setup guideline, data management policy, and forego using some of REDCap's features that may be highly useful, but do not allow a project to maintain Part11 compliance (e.g., non-standardized data elements, editing project fields post-Development beyond changes required through protocol amendments, PHI piping, public Project Dashboards, etc.)

If your project requires 21CFR Part11 compliance, be sure to reach out to a REDCap Administrator for assistance from the initial design phase of your new project.

#### **User Accounts**

How do I open/activate/request my REDCap user account?

This depends on whether or not you are an employee of Atrium-Wake, and which REDCap instance you are trying to access.

REDCap accounts are not universal across all instances. If you are an Atrium Health or Wake Health employee, your system credentials are your REDCap credentials, so you'll simply use them to log into your legacy institution's REDCap instance for the first time to activate your account:

**Atrium Health Main:** https://redcap.atriumhealth.org/redcap/ | https://rces.atriumhealth.org/redcap/

Wake Health Main: https://redcap.wakehealth.edu/redcap/

Wake Health CCC: https://redcap.wakehealth.edu/redcapccc/

**Atrium Health BCC:** https://rc2.atriumhealth.org/redcap/ | https://rc2e.atriumhealth.org/redcap/

If you are not an Atrium Health or Wake Health employee, then you will need to complete the respective External User Access Request Form:

External user needing access to an Atrium instances?: https://redcap.link/AHExtU

External user needing access to an Atrium instances?: https://redcap.link/WHExtU

User / Instance	Access AH	Access WH
Internal AH	Log in to REDCap Homepage with	Complete WH External User Request Form
	system	
Internal WH	Complete AH External User Request	Log in to REDCap Homepage with system
	Form	
<b>External Both</b>	Complete AH External User Request	Complete WH External User Request Form
	Form	

#### How do I log into REDCap?

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## Add user to the project

#### How can I add a new user to my project without the username populating?

Usernames are only populated once when users sign into the REDCap for the first time. For security reasons, REDCap administrators do not add users to your project. Therefore, you need to grant access other users to your projects by clicking on User Rights (left menu under Applications) and entering their username (not their email address). When the user you are adding has previously logged into REDCap, their name will appear in a drop-down menu. On the other hand, if they have never logged into REDCap, their name will not appear. However, you may still add users without populating their names, and you will have to add their usernames manually (instead of using the drop-down menu), or you may wait until the user logs into the REDCap. Then, you need to select the appropriate privileges.

### **User Rights**

# Could you please explain why the new instrument does not appear on my dashboard after it has been created in the production status of the project?

If new instruments are created in a project while in production status, all users and user roles will no longer automatically get full "View & Edit" rights. Instead, users will receive "No Access (Hidden)" rights by default for new instruments. For new instruments in the development status, the instrument level rights still will be "View and Edit" by default. This change helps improve security when a project is in production to ensure that users do not accidentally gain access to data that they should not see if new instruments are still being added to the project. To open up access to the new instrument after your current Draft Mode changes have been approved, ensure that all relevant users/roles have View/Edit rights. You can update user rights by selecting "User Rights" from the Applications menu on the left-hand side. You may also coordinate with the User Rights manager on the project to accomplish this.