SDSU | HealthLINK Endowment   **SDSU** | HealthLINK Center

SDSU REDCap Cloud (RCC) Project Request & User Management Procedures

ORIGINATING CORE OR GROUP/TEAM: MEASUREMENT METHODS GROUP (MMG)	
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EFFECTIVE DATE: JULY 22, 2022	**PRIOR PROCEDURE VERSION INFORMATION: (VERSION NUMBER, DATE):** N/A

PARTIES TO IMPLEMENT (CHECK ALL THAT APPLY):	
☐ SDSU HLINK CENTER (ALL)	☐ BBHP LAB
☐ ADMINISTRATION	☐ HDAG
☐ CRC	☐ IMG
☐ RIC	☐ HSMG
☐ IDC	☐ DAC
☐ CEC	☒ MMG
☐ BMG WET LAB	☐ IT

SCOPE:

This policy applies to all users (SDSU faculty, research scientists, and postdoctoral fellows) who wish to request a project under SDSU REDCap Cloud system, supported by the National Institute on Minority Health and Health Disparities of the National Institutes of Health under Award Numbers S21MD010690 (SDSU HealthLINK Endowment) and U54MD012397 (SDSU HealthLINK Center).

RELATED POLICIES/PROCEDURES:

REVIEWED BY SDSU HEALTHLINK CENTER STAFF MEMBERS:
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APPROVED BY SDSU HEALTHLINK CENTER CO-DIRECTORS:

Dr. Kristen Wells   **Dr. Guadalupe Ayala**

_____   _____

Summary of Changes

Version Number - Date	List Changes Here

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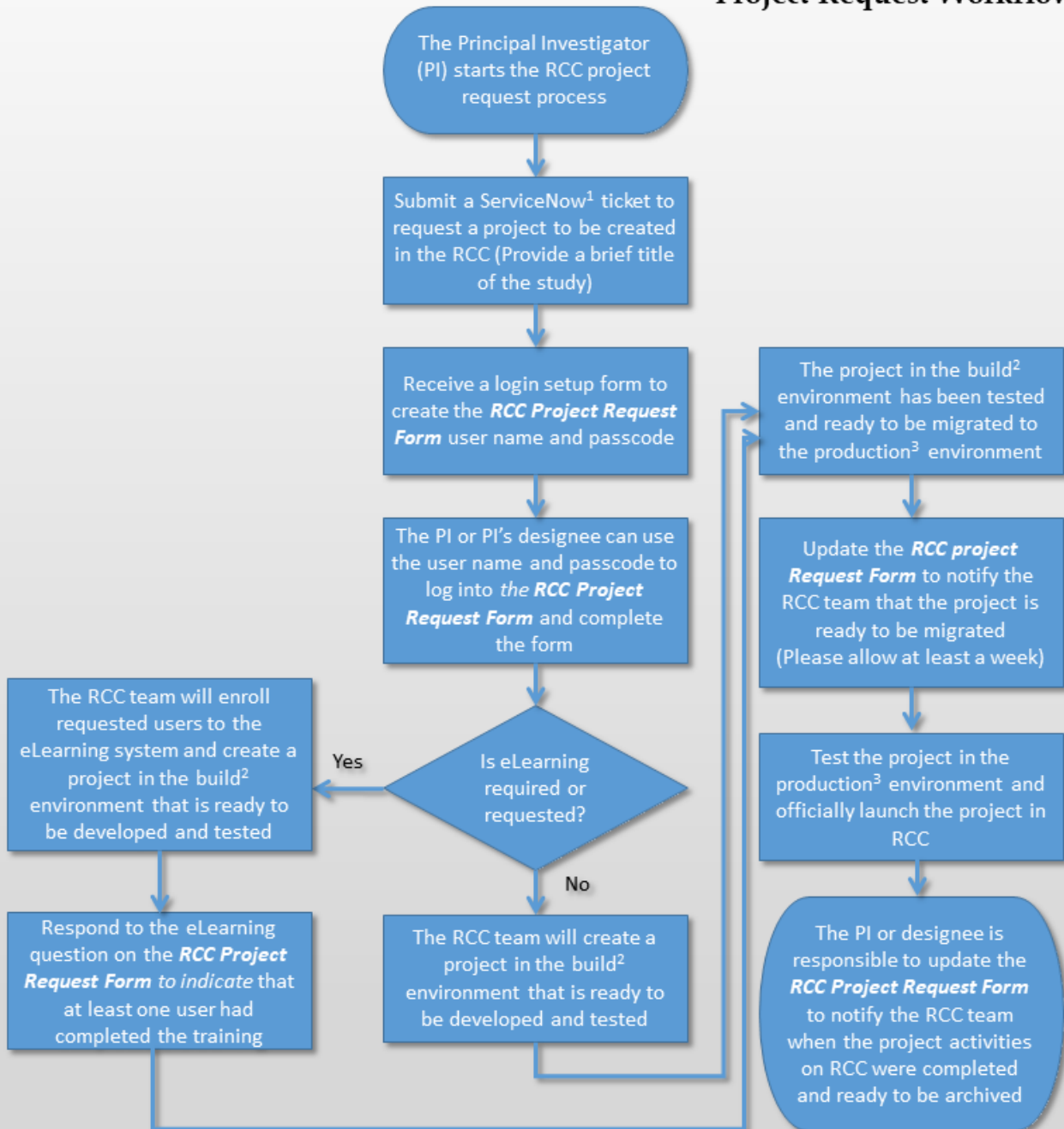# SDSU REDCap Cloud (RCC) Project Request and User Management Procedures

Please note that *REDCap Cloud (RCC) is available ONLY to **SDSU faculty members, research scientists, and postdoctoral fellows**.* We currently are not able to support student projects.

A few notes about creating a new project in RCC

1. For all new project requests, each study team will first be provided with a project in the RCC **build environment** which can be migrated to the **production environment** once all project setup and testing (e.g. instrument/survey creation, study group/site setup, randomization …etc.) are completed. The Principal Investigator (PI) or PI's trusted designee (e.g. Project Manager [PM], Project Coordinator [PC], or lead research assistant, student … etc.) should notify the RCC team to migrate the project from the build to production environment via RCC Project Request Form when they are ready to do so. **Each project MUST provide at least 1-week advance notice to transfer the RCC project from the build to production environment.** See below for definitions of the build/production environments:

   - **Build Environment:** All project design development work is done in build environment. Testing can be performed here as well. **No REAL** data (especially confidential data or Protected Health Information [PHI]) should ever be stored in the build environment.

   - **Production Environment:** This environment is used when you are finished building and testing your project design in the build environment and you are ready to commence live data collection.

2. Due to the storage limit of our RCC subscription, any file upload/image upload on participants' end is currently **PROHIBITED**.

A. RCC project request procedure flowchart diagram

REDCap Cloud (RCC) Project Request Workflow

The Principal Investigator (PI) starts the RCC project request process

Submit a ServiceNow[1] ticket to request a project to be created in the RCC (Provide a brief title of the study)

Receive a login setup form to create the **RCC Project Request Form** user name and passcode

The PI or PI's designee can use the user name and passcode to log into the *RCC Project Request Form* and complete the form

Is eLearning required or requested?

Yes → The RCC team will enroll requested users to the eLearning system and create a project in the build[2] environment that is ready to be developed and tested

Respond to the eLearning question on the **RCC Project Request Form** *to indicate* that at least one user had completed the training

No → The RCC team will create a project in the build[2] environment that is ready to be developed and tested

The project in the build[2] environment has been tested and ready to be migrated to the production[3] environment

Update the **RCC project Request Form** to notify the RCC team that the project is ready to be migrated (Please allow at least a week)

Test the project in the production[3] environment and officially launch the project in RCC

The PI or designee is responsible to update the **RCC Project Request Form** to notify the RCC team when the project activities on RCC were completed and ready to be archived

[1]**For research collaborators who do not have access to SDSU ServiceNow**, please contact the RCC team via email (healthlink.redcap@sdsu.edu).
[2]**Build Environment**: All project design development work is done in build environment. Testing can be performed here as well. No **REAL** data (especially PHI data) should ever be used in the Build Environment.
[3]**Production Environment**: This environment is used when you are finished building and testing your project design in the build environment and you are ready to commence live data collection.

B. Submitting a new project request via SDSU ServiceNow
- First, the PI of the project needs to submit a "**REDCap Cloud new project request**" ticket via SDSU ServiceNow and include a **brief title/acronym of the project** (character limit: 50).
- If you are unfamiliar with the SDSU ServiceNow system, follow instructions below to submit an incident in ServiceNow:
  - Go to SDSU ServiceNow homepage and use your SDSUid to log in and follow the steps below so the ticket can be automatically routed to the RCC team.

- Once the RCC team receives and confirms the new project request from ServiceNow, the PI will receive an email with a link to a "**Login setup form**" to set up the **RCC Project Request Form** username and passcode. After the username and passcode are created, another email will be sent to the PI with a personalized link to access the RCC Project Request Form.

> **Note**:
> PIs who have multiple projects in the RCC will have to follow this process for every project they wish to add to the RCC. Each project will have its own personalized link to the RCC Project Request Form. It is fine to have the same passcode across projects, but separate passcodes can also be set up for each project.
>
> It is important to save the personalized link to the RCC Project Request Form as a "**bookmark**" in the browser because the link can be used repeatedly to activate or deactivate users and make other REDCap Cloud related requests in the future. If the link was not saved, please search your email using this term, "**REDCap Cloud Project Request Form**," and the initial email with the link to this form should appear.

Please also note that the PI or a trusted designee (e.g. Project Manager [PM], Project Coordinator [PC], or lead research assistant, student… etc.) will need the login information (i.e., **username and passcode**) to access the RCC Project Request Form to provide project information and manage users in REDCap Cloud. The PI is ultimately responsible for any project staff to be activated/deactivated from the RCC project. Please save the login information in a secure place and only share the username and passcode to a trusted designee if the PI prefers to have a designee to manage the RCC project user accounts.

- The PI and/or the designee should be the only individual(s) who have access to the form to request users to be activated/deactivated since they are responsible for granting project staff access to Protected Level 1 (PL-1) data or HIPAA data that may be collected within the RCC system.
  - See SDSU's definition of PL-1 data here: https://education.sdsu.edu/faculty-staff/help-desk/data-classification-and-handling-policies
  - See definition of HIPAA data here: https://www.hipaajournal.com/considered-phi-hipaa/

    > **Note**: The RCC server is HIPAA complaint; thus, confidential data or PHI can be safely stored within the RCC system.

C. Completing and submitting the REDCap Cloud project request form
- The form consists of a few sections:
  - Project Information
  - eLearning Enrollment
  - Knowledge Base
  - User Activation and Deactivation
  - Transferring Build Project to Production Environment
  - Project Archive

i.   *Project Information*

- In this section, the requestor will need to fill out requestor name, email, and position, as well as project name, title, and description, as well as other project related information. The image below shows a snapshot of the form. It is important to read and answer all questions as they are needed to set up the project in RCC.

ii.   *eLearning Enrollment: Required or Requested eLearning Lessons*

- RCC offers eLearning lessons for users to learn about the features of RCC and how to build a project in RCC. The PIs or designees will be asked whether the research team has a user who knows how to build a project in RCC (see image below).

- If no one from the project has experience in building/developing a project in the RCC, we **require** the PI or designee to assign at least one person from the team to the RCC eLearning system.
- The PI or the designee could also request any project staff to be enrolled in the eLearning system even if one or more users from the team already know how to build a project in the RCC.
- RCC has predetermined the following lessons for users who wish to learn how to develop a project in the RCC:
  - Basics 1: Study Parameters

- o Basics 2: Study Build
- o Basics 3: Study Team Roles, Permission and User Assignments
- o Basics 4: Enroll and Data Capture
- o Basics 5: Data Export, Reporting, Audit Logs
- o Basics 6: Intermediate Reporting (create a report within and across instruments)
- o Basics 8: Query Management
- o Basics 9: Surveys (not in-person data collection; sending an instrument via a link)
- o Basics 12: Rules (automatically triggering actions such as notifications)
- o Basics 13: Study Groups & Randomization
- o Basics 14: eSignature Process
- The estimated length of time to complete the training is about 16-20 hours depending on the pace of the eLearners.
- The RCC team will also provide an "**FAQ for REDCap Cloud**" to each research team. We highly encourage the team member to read this document prior to building your own project.
- If your research team is required to complete the eLearning lessons, **you will need to return to the request form later and indicate that at least one of your research team members completed all required lessons by answering the question below and providing your signature**. The RCC team will be notified automatically when the response to the question and the signature were provided.

eLearning Lessons Completion

Has at least one of your research team members completed ALL required RCC eLearning lessons?
(elearning_completed)
[Branching logic exists]

○ No
○ Yes

Your signature indicates that at least one of your research team members has completed all RCC eLearning lessons and your team has a basic understanding of how to build a project in the RCC.
(elearning_train_sig)
[Branching logic exists]

iii. Knowledge Base/Community Forum

- RCC's knowledge base provides you access to user guides that discuss the functionalities of RCC.
- All users have access to knowledge base. Here are the instructions to access REDCap Cloud (RCC) Knowledge Base:
    - o After logging into the REDCap Cloud Build or Production environment, click the "Support" tab on the left panel of the screen (see figure below).
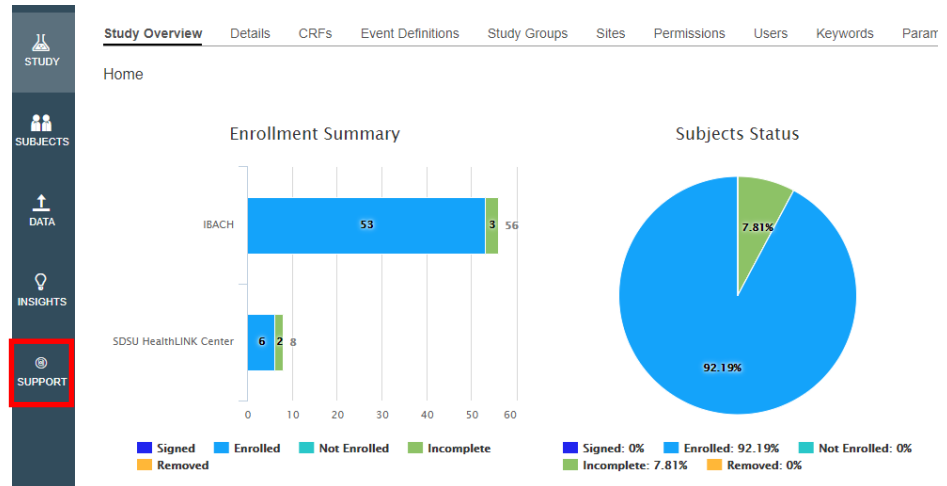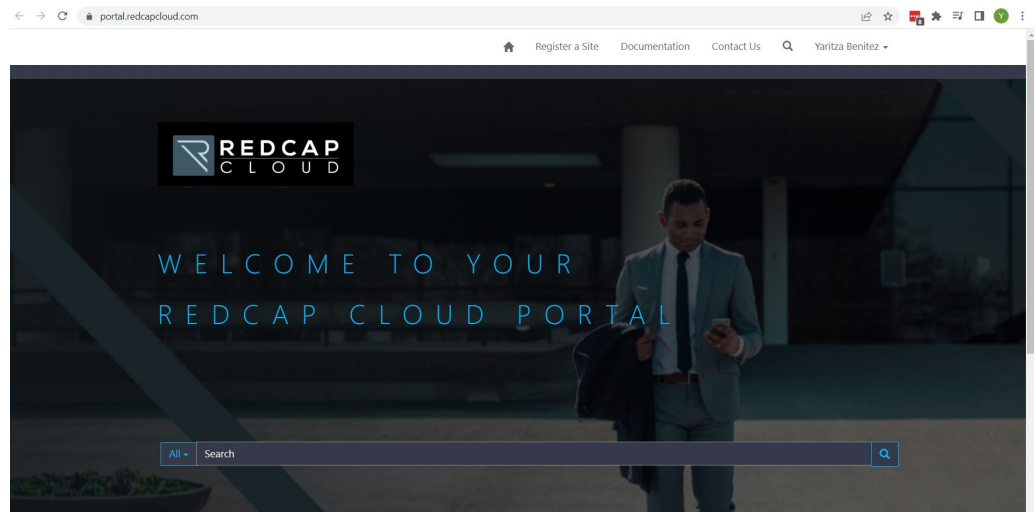
o   Click on the "**Support**" tab below the study name (i.e. "Testing" in the example below).
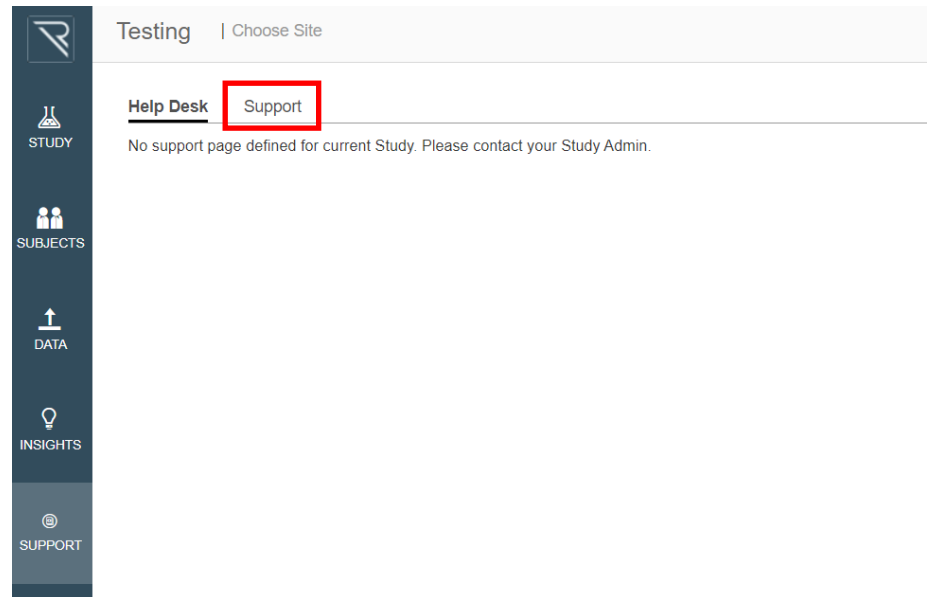
o   Once in the support tab, click on the icon.

Click here to access the new REDCap Cloud Community and Support portal
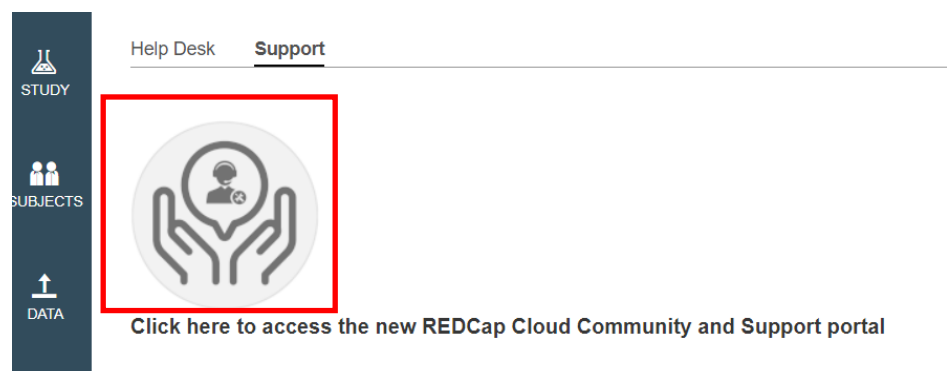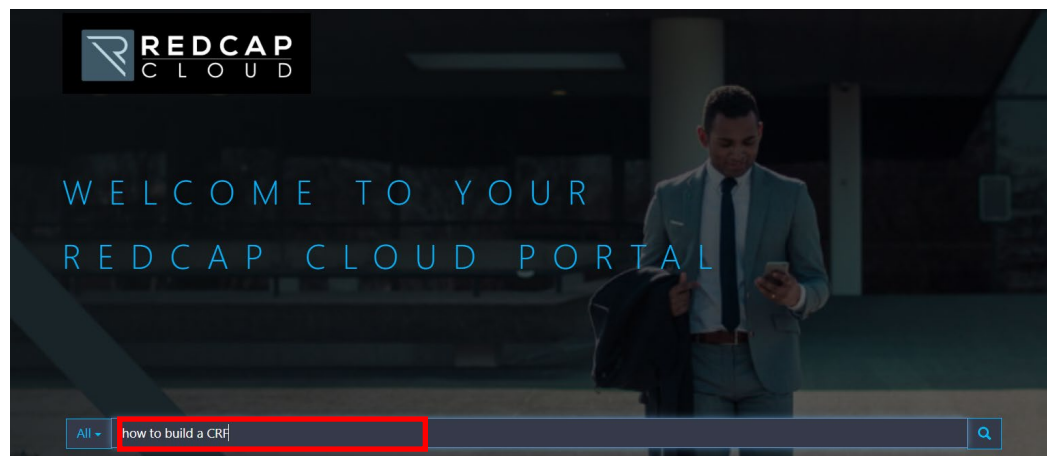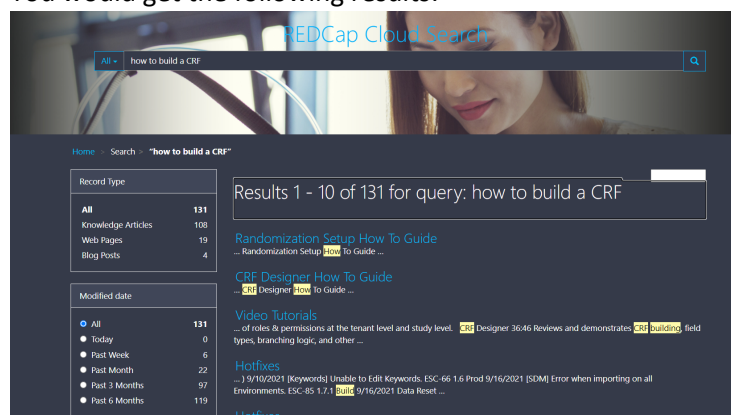
o You will now be directed to REDCap Cloud Knowledge Base website (see image below)

o Using the search bar in the website, you can search for knowledge base articles that RCC offers. For example, if you search "how to build a CRF"
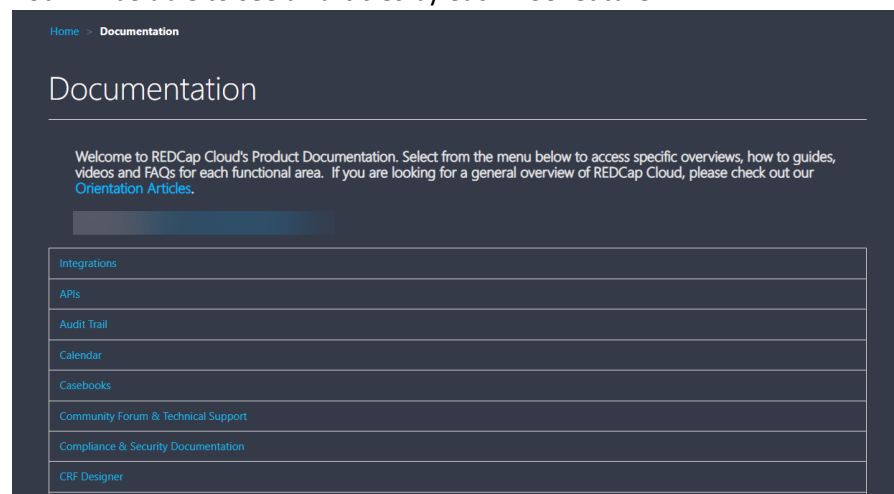

o You would get the following results:

- o Alternatively, you can access and browse through all the articles that RCC has available by clicking on "Documentation"
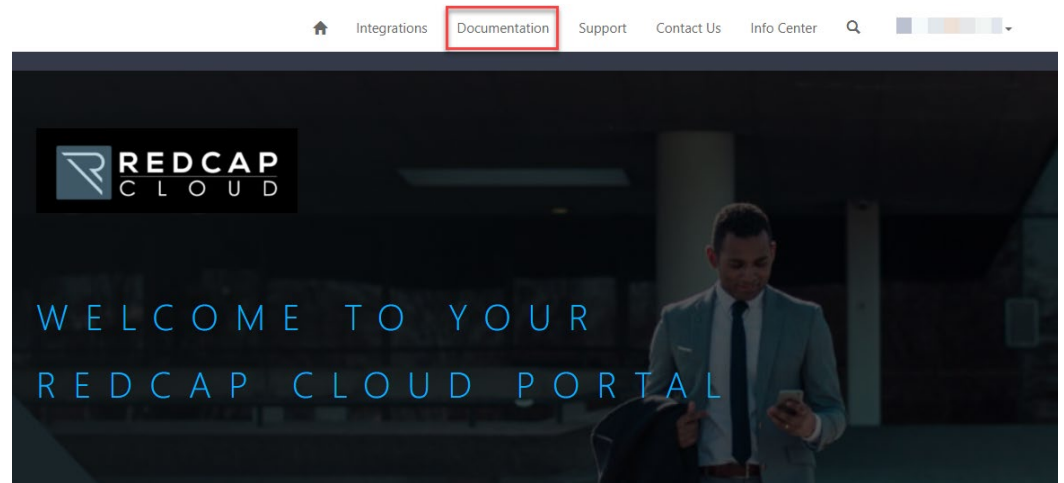
- o You will be able to see all articles by each RCC feature.

iv. User Activation and Deactivation

- New user requests can be entered in four separate roles in the RCC project request form:

  - o **Principal Investigator (PI) Role**: Users with this role have access to almost all functions of the RCC, with the exception of functions that only the RCC team have: activating/deactivating users, updating permissions, migration plans of the study, sending IT support, and access to changing study status and version.
  - o **Project Coordinator/Manager (PC/PM) Role**: Users with this role have the same access as the principal investigator; the only difference is the title of the role.
  - o **Research Assistant (RA) Role**: Users with this role have access to edit and enter information into the instrument/CRF; screen and enroll subjects; schedule/remove events, but they do not have access to features such as data delete or Protected Health Information (PHI) permissions (unless specified).

- o **Screener Role**: Users with this role have access to edit and enter information into the instrument/CRF; screen and enroll subjects; and view/edit the calendared events.
- o For a list of detailed permissions assigned to each role, please click here.

> **Note**: If additional role(s) other than the four roles specified above is/are needed, there is a section in the form to add notes regarding the roles (see below). Please consult with the RCC team regarding why a new role is needed. Once the RCC team and the PI/designee determine that an additional role is needed for the project, the "**Other Role**" section will be added to the request form where you could activate/deactivate a user under the "other role."
>
> If any, please address your questions/concerns about the roles and permissions here.
> *(roles_concerns)*

- The PI or designee will need to enter new users' full name and institutional email (if SDSU/SDSURF faculty/staff/student, enter SDSUid) in the appropriate field to activate a user.
- Please also note that only essential users need to be added to the build environment to develop and test the project (e.g. staff who will help create/test the instrument, design the project, set up randomization…etc). For example, a data entry research assistant will **NOT** need to be added to the build environment. These users can be later activated in the same form after the project is transferred from the build to production environment.
- In addition to activating new users, the PI or designee is able to edit the request form in the future to change the user's status to "**inactive**" on the form. This is why it is important to save the personalized link of the RCC Project Request Form and its associated username and passcode. Follow the instructions on the form to deactivate a user.

> **Note:**
> When the user status was changed (e.g. change to Active/Inactive), the RCC team will be notified automatically and you will be informed once the requested change has been made.
>
> It is **IMPORTANT** for the PI or designee to deactivate research team members' accounts when they leave the team. This is to prevent non-project related users having unauthorized access to your project's data.

- While the build/production accounts do expire for non-faculty SDSU users and external research collaborators, the PI or designee will be able to request the RCC team to renew user account by indicating "Yes" to the following questions:

- o Do you wish to renew this SDSU user's BUILD account?
- o Do you wish to renew this EXTERNAL user's BUILD account?
- o Do you wish to renew this EXTERNAL user's PRODUCTION account?

> **Note:**
>
> When "Yes" was selected for the any of the questions above, the RCC team will be notified automatically, and you will be informed once the user was renewed.
>
> If it is the first time you are completing the form, you can indicate "No" for this question.

- If there are any special notes or instructions for any of the users who are activated/deactivated, there is a notes section where you can indicate any changes made to the current user or any special instructions needed for the RCC team. For example, if a user's role was changed from one to another (see image below) or a users' email has been changed, you can insert a note to indicate the change(s) or add special instructions there.
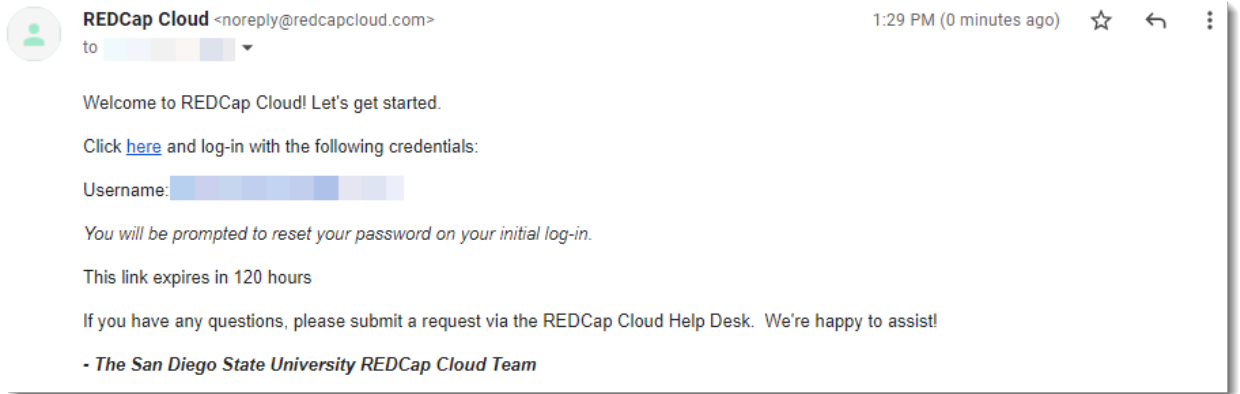

D. Activating the new project & new users in the build environment
   i. *Build account creation process*
      - Once the RCC project request form was submitted, the RCC team will create the requested project in the build environment and users included on the form will be added to the project.
      - After all the new user accounts are created, an email to the users will be sent from the **RCC Build** system (See image below). Users are given **3 working days** to sign into their accounts. They will have 24 hours to reset their password and log in.
         - o Each user's log in name will have "**.build**" attached to their user name before "@sdsu.edu" (For example, **jdoe.build@sdsu.edu**)

REDCap Cloud <noreply@redcapcloud.com>   1:29 PM (0 minutes ago)   ☆   ↩   ⋮
to ▮▮▮▮▮▮ ▾

Welcome to REDCap Cloud! Let's get started.

Click here and log-in with the following credentials:

Username: ▮▮▮▮▮▮▮▮▮

You will be prompted to reset your password on your initial log-in.

This link expires in 120 hours

If you have any questions, please submit a request via the REDCap Cloud Help Desk. We're happy to assist!

- The San Diego State University REDCap Cloud Team

- Users will **NOT** be able to log in after the 3 working days limit. After 3 working days, the PI or designee must make a request to the RCC team via SDSU ServiceNow to reset user's account if the allowable login days have been expired.
- The maximum password retries is set to 5.
- External research collaborators are allowed to have a build/production account created; however, certain restrictions apply.
  - The SDSU PI (e.g., SDSU faculty, adjunct faculty) **MUST** be the primary grant receiver for the funded project or the primary investigator for an unfunded project in order to add external users.
  - The PI or designee **MUST** make a request for external users to have access to the RCC.
  - The PI or designee **MUST** provide external user's education/institutional email account (no personal e-mail accounts allowed) in the RCC Project Request Form.
- While eLearners are completing the lessons, they will be able to use the build environment to follow along the lessons.

ii.   *Build user/project account expiration and deactivation*
- Build user account expiration
  - **SDSU faculties:** Their account do not expire unless they separate from the University.
  - **SDSU non-faculty users**: Their accounts will expire **ONE YEAR** from the account activation date.
  - **External research collaborators:** Their accounts will expire **ONE YEAR** from the account activation date.
  - The PI or designee is highly encouraged to keep track of their users' expiration date so they can renew users' account in advance by requesting the account renewal in the User Activation and Deactivation section of the request form.
  - All types of accounts are subject to the account automatic deactivation rule described below.
- Build user/project account automatic deactivation
  - The RCC team will audit all projects and user accounts on an annual basis (Fall semester; Mid-September).
    - If there is no user account activity within the last 6 months, the user account will be deactivated.
    - If there is no project activity within the last 6 months, the project will be **LOCKED**. See what RCC functions will be disabled in the locked status here.

- The PI or designee can make requests to the have the project unlocked and/or user account re-activated.

E. Transferring the build project to the production environment
   i. *Build to production transferring request*
   - After the project has been completely developed and tested in the build environment and ready to be transferred to the production environment, the PI or designee can indicate this in the request form (see image below) so the RCC team can be notified to migrate the project from the build to the production environment.

TRANSFERRING BUILD PROJECT TO THE PODUCTION ENVIRONMENT

Is your project ready to be transferred from the build to production environment?
○ No
○ Yes
Reset

Note: If it is the first time you are completing the form, you can indicate "No" for this question. When your project is ready to be transferred, please change your response to "Yes."

- Please provide at least **ONE WEEK** advance notice for the migration to occur. When migration occurs, the test participants enrolled in the build environment **WILL NOT** be transferred over. Only the "**project design/configuration**" (e.g., group randomization, rules, CRFs/instruments, survey setup, sites, event definitions, permissions…etc.) will be transferred.

Note:
Please be sure to inform the research team members **NOT** to log in or make any changes in the build environment after the transfer request is made.

If your projects involves the use of random assignment, the **randomization configuration** will need to be set up again after the project has been transferred to the production environment.

- If the project is ready to be transferred, the PI or designee must also indicate whether ALL users from the build environment will be transferred to the production environment. If not, the PI or designee should indicate "no" to the question shown in the image below and add a note for each user who will be transferred to the production environment.

Note: Unless specified, user(s) will only be activated in the production environment if user activation request was made **AFTER** the project has been transferred to the production environment. However, the PI or designee can indicate in the notes section if the new user also needs to be activated in the build environment. See example below:
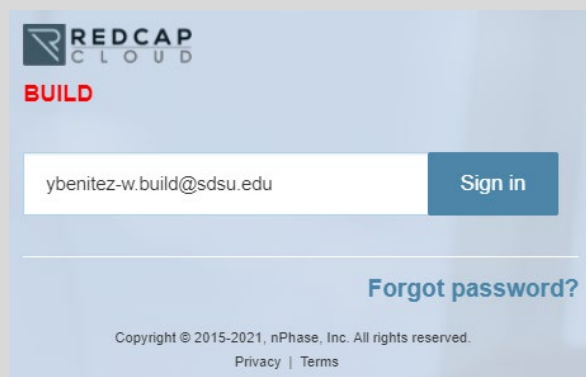

F. Activating the new project & new users in the production environment

After the project has been migrated from the RCC build to production, the RCC team will ensure that all the project users are activated in the production environment.

Note: Activating users in the build vs. production environment is a different process. Having an account in the build environment does not grant users access to the production environment. Logging in to the build or the production environment is also different

Build environment log-in window:

Note the web address for the build environment contains the word "build": **build**.redcapcloud.com. The word "**BUILD**" is also shown in the log-in screen and "**.build**" is attached to the end of user name (see example below).

Production environment log-in window:

Note the web address for the production environment contains the word "login": **login**.redcapcloud.com
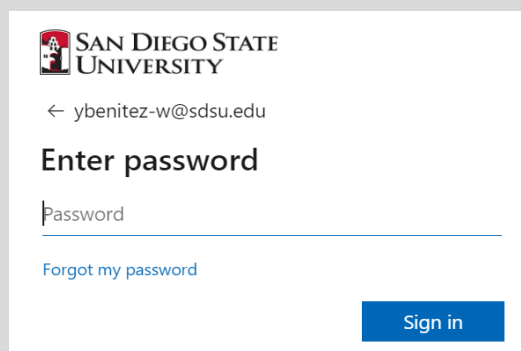The word "BUILD" is **NOT** shown in the log-in screen.

Login for SDSU users:
SDSU users will use their SDSUid to log in to the production environment. Once users enter the user name and click on "**Sign in,**" it will re-direct users to the SDSUid login page where users would normally enter their SDSUid password (see below) and authenticate the identity via DUO.
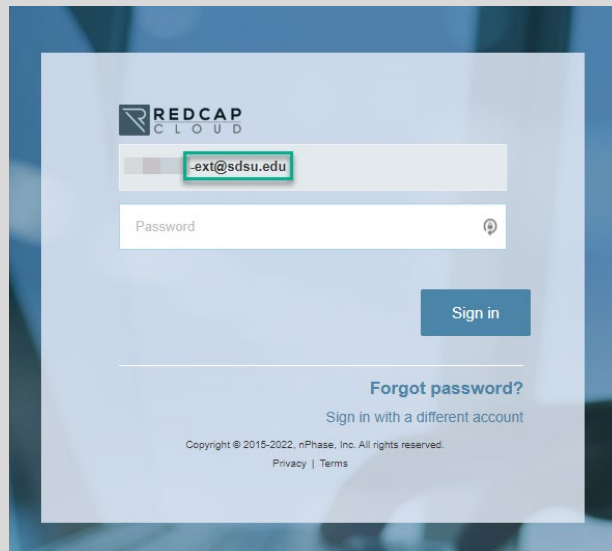

### Login for external research collaborators:
External user will **NOT** use SDSUid to log in to the production **environment**. They will have

"**-ext@sdsu.edu**" attached to the end of the user name (see example below) of their production accounts. Once the user name has been entered, users will see the regular REDCap Cloud login screen to enter the password.
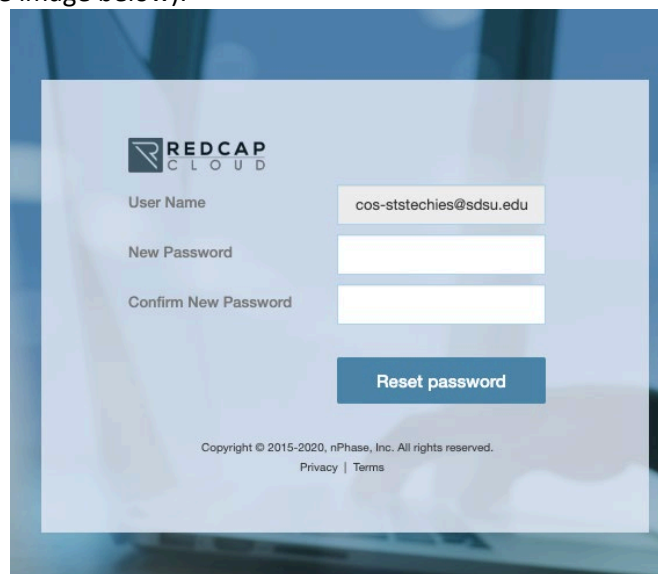

i.   Production account creation process

- **SDSU Users (faculty and non-faculty users)**
  - The users will receive an email from the RCC team to log in once to the REDCap Cloud Production Site (https://login.redcapcloud.com) to complete the account creation. Users will just need to log in with their SDSUid.
  - **IMPORTANT**: SDSU users will need to reply to the email to note that they have logged in once.
  - Upon receiving the email from the users, the RCC team will be able to add the user(s) to the appropriate project in the production environment.
- **External Research Collaborator Users**
  - External research collaborators (e.g. external clinical partners) may also be eligible to have accounts activated in the RCC production environment.
  - New external users will be given 3 working days to sign into their account.
  - An automatic email to the external user will be sent by the RCC system. The user will have 24 hours to reset their password and log in.
  - If external users attempt to login after the allowed time period, they will not be able to log in and the PI (via SDSU ServiceNow) or designee (via email: healthlink.redcap@sdsu.edu) must make a request to the RCC team to reactivate the link.
  - The maximum password retries is set to 5 attempts.
  - Please note that while external users do not have an SDSU "single sign-on (SSO)" account, the RCC system will send an email to the user with a user name and a link to update the password (see image below).
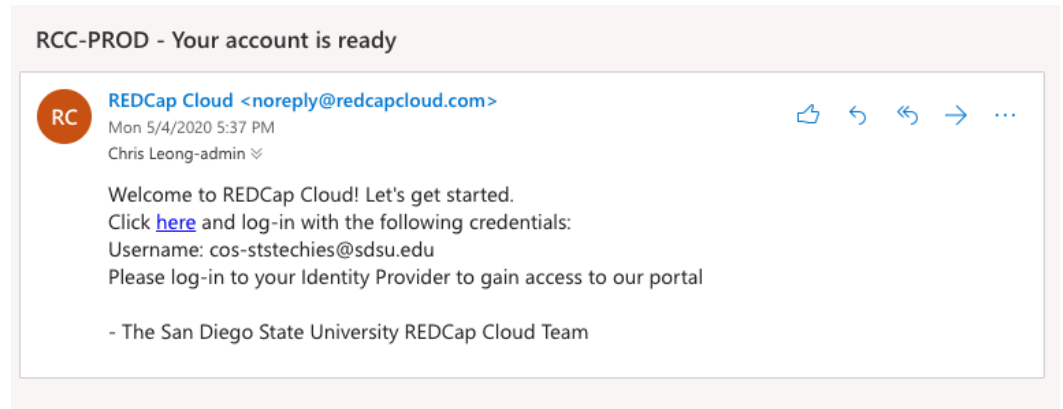
o   A password can be generated when external users first log in to their account (see image below).

ii.   *Production user/project account expiration and deactivation*
- Production user account expiration
  o   **SDSU faculty and non-faculty users**: Their accounts do not expire unless they separate/graduate from the University; however, SDSU user accounts are subject to the account automatic deactivation rule describe below.
  o   **External research collaborators**: Their accounts will expire **ONE YEAR** from the account activation date. The PI or designee is highly encouraged to keep track of their users' expiration date so they can renew users' account in advance by requesting the account renewal in the User Activation and Deactivation section of the request form.
- Production user/project account automatic deactivation
  o   The RCC team will audit all projects and user accounts on an annual basis (Fall semester; Mid-September).
    ▪   If there is no user account activity within the last 6 months, the user account will be deactivated.

- If there is no project activity within the last 6 months, the project will be **LOCKED**. See what RCC functions will be disabled in the locked status [here](#).
- The PI or designee can make requests to the have the project unlocked and/or user account re-activated.

Table 1 below summarizes the expiration dates for both build and production account/project.

Table 1. RCC build and production environment user/project account expiration and deactivation

	Build Environment	Production Environment
User account expiration (SDSU faculty accounts do not expire unless they separate from the university).	SDSU non-faculty users & external research collaborators: Their accounts expire **one year** from the account activation date.*	• SDSU non-faculty users: No expiration unless graduate/separate from the University. • External research collaborators: Their account expire **one year** from the account activation date.*
User account automatic deactivation	Deactivated if no user activities within the **last 6 months** during the annual audit.*	Deactivated if no user activities within the **last 6 months** during the annual audit.*
Project automatic deactivation (Locked status)	Deactivated if no project activities within the **last 6 months** during the annual audit.§	Deactivated if no project activities within the **last 6 months** during the annual audit.§

*Accounts can be renewed upon request
§Projects can be unlocked upon request

iii. RCC administrator accounts

- College of Science [Chris Leong] and College of Health and Human Service [Brian Lenz] IT personnel and the RCC team members [Dr. Shih-Fan (Sam) Lin & Yaritza Benitez] will be added as administrators to all projects on the RCC build/production environments so they can provide technical support when needed.
- All SDSU technical support personnel will have access to the project data. According to SDSU IRB, IT personnel and RCC team **DO NOT** need to be added to the study IRB as their roles are service provision.
- It is possible that additional HealthLINK or REDCap Cloud support staff may be added to the project to provide technical support; however, permissions to add the additional support staff will first be obtained from the PI or designee.

G. Project archive

The PI or designee is responsible to notify the RCC team when the project activities on the RCC were completed by indicating "**Yes**" to the question in the request form (see image below). Once notified, the RCC team will change the project to the "Locked" status. The PI or designee will need to ensure that the project datasets were downloaded as datasets cannot be downloaded after the study status is changed to "Locked."

> **Note**: If it is the first time you are completing the form, you can indicate "No" for this question. When your project activities are completed and ready to be archived, please change your response to "Yes."

H. RCC technical support contact

- The RCC does not allow individual users to contact their company support team directly. All technical support issues should be first submitted to our internal SDSU RCC team. If our SDSU team is not able to resolve your issue(s), a support ticket will be submitted to the RCC company support team. Please allow at least 3-5 days for our SDSU RCC team to get back to you. If the issue is time sensitive, please indicate so in your request. In you description, please ensure the following information is included:
  - Project Name
  - Whether the issue is related to **build** or **production** environment
  - Description of your problem(s) or issue(s)
  - A screen shot of the error message you received or a screenshot/video of the problem you encountered
- For **SDSU users**, the request should be made via SDSU ServiceNow. Please make sure that you **ALWAYS** include the word "**REDCap Cloud**" in the "**How can we help you?**" field so the ticket gets routed to the REDCap Cloud team appropriately (see image below).

  - For **external research collaborators**, the technical support request can be made via email: healthlink.redcap@sdsu.edu

I. Acknowledging REDCap Cloud Support in Research Products

- As the funding and support is provided by the SDSU HealthLINK Endowment and SDSU HealthLINK Center, it is required that the support must be cited in all research products (e.g. presentations, posters, publications...etc.). See below for suggested funding statements to be included in your research products: