REDCap
in a multicenter trial

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APPEX-19

◦ Multicenter, international randomized control clinical trial assessing the effectiveness of self-prone positioning at reducing respiratory deterioration in patients with COVID-19

◦ Designed to be conducted in a pandemic setting

◦ Relies heavily on REDCap for remote consent and data collection

NIH› U.S. National Library of Medicine
ClinicalTrials.gov

Awake Prone Position for Early Hypoxemia in COVID-19 (APPEX-19)

ClinicalTrials.gov Identifier: NCT04344587

⚠ The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

Recruitment Status ❶ : Enrolling by invitation
First Posted ❶ : April 14, 2020
Last Update Posted ❶ : November 10, 2020

Multicenter Technical Issues

How do I distinguish between patients enrolled at a specific sites?

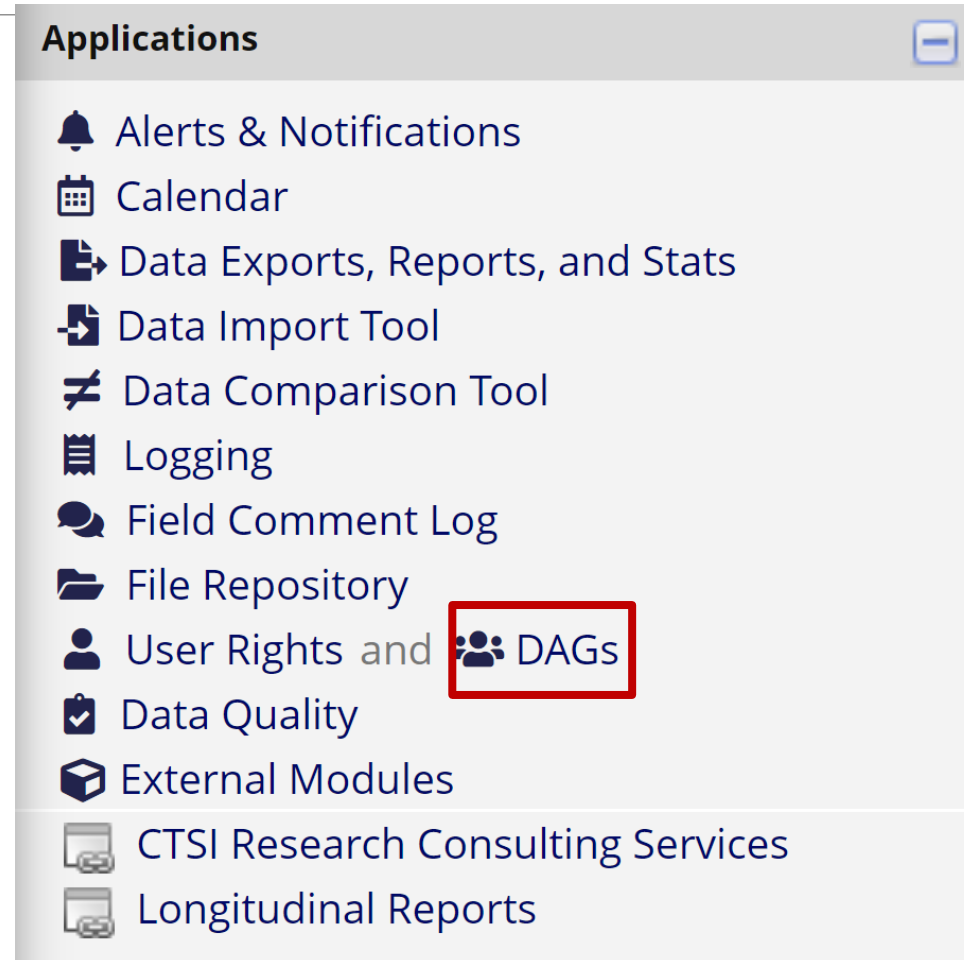How do I limit patient data entered from one site from being viewed at another site?

Data Access Groups (DAGs)

Identifies group and restricts viewing of data within a database

◦ A 4-digit code identifies records entered from a specific DAG

◦ Users can only interact with records they created or created by other users in the same DAG

  ◦ Apply to all non-core study staff at the primary site

◦ Users not assigned to a DAG can see <u>ALL</u> data across all sites

  ◦ Apply to PI and core study personnel from the primary site

Essential for multicenter projects

Creating DAGs and Assigning Users

DAGs

Create new groups: Add new data access groups to which users may be assigned.

+ [Enter new group name] [Add Group]

Assign user to a group: Users may be assigned to any data access group.

Assign user [-- Select User --] to
[No Assignment] [Assign]

Data Access Groups	Users in group	Number of records in group	Unique group name (auto-generated)	Group ID number	Delete group?
Alvarado	⬛	0	alvarado	1671	✖
Baylor College of Medicine	⬛ Verma)	18	baylor_college_of	1580	✖

Create data reports by site

Applications ⊟

🔔 Alerts & Notifications

📅 Calendar

📥 **Data Exports, Reports, and Stats**

📥 Data Import Tool

≠ Data Comparison Tool

📋 Logging

💬 Field Comment Log

📂 File Repository

👤 User Rights and 👥 DAGs

✅ Data Quality

📦 External Modules

🖥 CTSI Research Consulting Services

🖥 Longitudinal Reports

👤+ User Access: Choose who can edit and view this report

👁 View Access: Choose who sees this report on their left-hand project menu ❓

○ **All users**   – OR –   ⦿

Custom user access   (Users in ANY groups selected below will have access)

Selected users

aabebe.kumc (Abebe Abebe)
aberical (Andrew Berical)
agforema (Alexis Gallardo Foreman)
ajabowser.piedmont (Aja Bowser)

Selected user roles

BU Data Entry
Core Personnel
Off-site Data Entry
Principal Investigator

Selected DAGs

Alvarado
Baylor College of Medicine
Baylor Scott and White
Boston University

View a list of users who will have access to this report based on the selections above: [View user access list]

✏ Edit Access: Choose who can edit, copy, or delete this report (requires user to have 'Add/Edi

○ **All users**   – OR –   ⦿

Custom user access   (Users in ANY groups selected below will have access)

Selected users

fhoney.respireresearch (Faith Honey)
flygrrl.umich (Kristine Nelson)
franklinnduku.va (Franklin Nduku)
garcia89 (Michael Garcia)

Selected user roles

BU Data Entry
Core Personnel
Off-site Data Entry
Principal Investigator

Selected DAGs

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Baylor College of Medicine
Baylor Scott and White
Boston University

View a list of users who will have access to this report based on the selections above: [View user access list]

Data Reports

Patient Study ID patient_study_id	Event Name redcap_event_name	Repeat Instrument redcap_repeat_instrument	Repeat Instance redcap_repeat_instance	Date Randomization Assignment Completed? date_randomization	Which study arm is the patient randomized to?
1584-8	Enrollment			05-28-2020	Control (usual care) (0)
1584-9	Enrollment			05-28-2020	Intervention (prone positioning) (1)
1589-6	Enrollment			05-31-2020	Intervention (prone positioning) (1)
1589-7	Enrollment			05-31-2020	Intervention (prone positioning) (1)
1582-3	Enrollment			06-01-2020	Control (usual care) (0)

Multicenter Technical Issues

How do I change database privileges between core PI's, site PI's and data entry minions?

User Rights

Allows the Project Owner to designate privileges to other project members

Don't give users more access than they need!

Basic Rights

Role name: Site Leader

Highest level privileges:

- Project Design and Setup ☐
- User Rights ☐
- Data Access Groups ☐

Privileges for data exports (including PDFs and API exports), reports, and stats:

- Data Exports
  - ○ No Access
  - ○ De-Identified*
  - ● Remove all tagged Identifier fields
  - ○ Full Data Set

  * De-identified means that all free-form text fields will be removed, as well as any date/time fields and Identifier fields.

- Add/Edit/Organize Reports ☑
  Also allows user to view ALL reports (but not necessarily all data in the reports)

Settings pertaining to project records: Explain these settings

- Create Records ☑
- Rename Records ☐
- Delete Records ☐

Data Entry Rights

NOTE: The data entry rights *only* pertain to a user's ability to view or edit data on a web page in REDCap (e.g., data entry forms, reports). It has no effect on data imports or data exports.

	No Access	Read Only	View & Edit	Edit survey responses
Patient Consent Form (survey)	●	○	○	☐
Study Personnel Consent Form (survey)	●	○	○	☐
Enrollment	○	○	●	
First EMR Data Collection	○	○	●	
Daily EMR Assessment	○	○	●	
Daily Body Position Assessment	●	○	○	
Text Terminations	●	○	○	

User Rights

Add new users: Give them custom user rights or assign them to a role.

Add new user | Add with custom rights

— OR —

Assign new user | Assign to role ▽

- ➡ BU Data Entry
- ➡ Core Personnel

Create new roles: Add new user roles to w

Enter new role name

(e.g., Project Manager, Data Entry Perso

- ➡ Off-site Data Entry
- ➡ Principal Investigator
- ➡ Site Leader

Role name (click role name to edit role)	Project Design and Setup	User Rights	Data Access Groups	Data Export Tool	Reports & Report Builder
Site Leader	✖	✖	✖	Remove all tagged Identifier fields	✔
Principal Investigator	✔	✔	✔	Full Data Set	✔

Multicenter Technical Issues

Can I create different questions/instruments for different sites within the same project?

Site Designation

Branching logic for site-specific questions

Variable: emr_inclusion_criteria   *Branching logic:* [hospital_site] = "0"

EMR Inclusion Criteria (Check all that apply)

* must provide value

- ☐ Age >= 18 years
- ☐ Admitted or planned admission to a COVID-19 ward team
- ☐ Admitted within the last 24 hours
- ☐ English or Spanish-speaking

Please confirm that patient meets all inclusion criteria

Variable: inclusion_exclusion   *Branching logic:* [hospital_site] <> 0

Meets all inclusion criteria and does not meet any exclusion criteria

* must provide value

- ○ Yes
- ○ No

Multicenter Technical Issues - Solved

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Can I create different questions/instruments for different sites within the same project?

Lessons Learned

Practice! – Pre-production is your sandbox to experiment

◦ Assign study personnel to different DAGs, create records, create reports, view the data

◦ Practice records can be deleted before going live

The simplest solution is the best solution

◦ Branching logic adds sophistication but can also add unnecessary headaches

Questions?