



MyCap Guide for End Users

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Table of Contents

Definition of MyCap.....	4
Document Scope	4
MyCap Project Life Cycle.....	4
Participant experience: start to finish	4
Participant parameters	5
Multiple MyCap project participants	5
Communication with Participants	5
Project Creation.....	6
Enabling MyCap on an existing project.....	6
User permissions specific to MyCap projects	6
MyCap design.....	7
Custom Themes.....	7
Introductory Screens	7
Project-Specific Introduction Screens.....	7
Security Screens.....	8
Permissions Screens.....	9
Project Design specific to MyCap projects.....	10
Features Supported/Unsupported in MyCap.....	10
Fields Supported/Unsupported in MyCap	10
Task & Active Task	12
Active Tasks	12
Active tasks in ResearchKit (for iOS devices)	13
Active Task Examples	15
Scheduling Tasks.....	15
Install Date	15
Baseline Date.....	15
QR Codes explained.....	16
Anatomy of a QR code	16
Generating a QR code for a participant	16
Distributing a QR code to a participant	18
Participant removal	18
Participant removal from a study.....	18
Participant removal from a specific MyCap project	18
Consenting participants	18
Viewing collected data.....	18

Example MyCap projects	18
Tablets pre-loaded with MyCap	18
Operational use	18
COVID research case	19
To demo MyCap	19
Appendix	19
Deciding which platform to use.....	19
Compare and Contrast: MyCap vs REDCap Mobile app vs. traditional REDCap project.....	19
MyCap vs. traditional REDCap project	20
When MyCap is not recommended	20
IRB Approval.....	20
Technology	20
Internet requirements	20
Offline Capabilities.....	20
Security features of MyCap	21
MyCap and 3rd party services	21

Definition of MyCap

MyCap is an external module that can be enabled on a REDCap project and is designed for studies that have a pre-identified set of study participants who will need to provide data on a regular basis and who prefer to communicate via a tablet or mobile phone. The MyCap app is compatible for both iOS and Android devices (cell phones and tablets). For more information about MyCap you can visit the MyCap website at <https://projectmycap.org/>

Document Scope

This document is designed to provide an overview of the MyCap module and to answer some of the basic questions about when to use it, how to set up a project, how to add participants, and keeping data secure. Please note that currently these features are available only by enabling the MyCap external module. However, there are future plans to integrate them into the basic REDCap project.

MyCap Project Life Cycle

Below is a high level overview of the steps in a MyCap Project Life Cycle. For more information about each step, read further down.

1. Confirm with your institution's regulatory board that the use of MyCap is acceptable for your specific study.
2. Request your REDCap administrator to create a MyCap-enabled REDCap project for you.
3. Design your REDCap project
4. Design the MyCap interface
 - a. Schedule when and how often tasks/survey should appear.
 - b. Create information screens.
 - c. Create a custom theme.
5. Test MyCap with colleagues.
6. Move project to Production, just as you would with a regular REDCap project.
7. Give unique QR code to participant. This QR code will bring them to the appropriate project.
8. Participant downloads MyCap app and joins the project by scanning the QR code.
9. The device pulls from the server the REDCap project configuration into the participant's device.
10. Participant receives push notifications set up by user.
11. Participant enters data via the app.
12. Once study ends, participant uninstalls the app or deletes the project from the app (if they are participating in multiple MyCap studies)
13. Move your project to Analysis mode.

Participant experience: start to finish

1. After providing consent, a survey participant will receive a QR code from the research team.
2. Participant goes to the app store on their device and downloads the MyCap app
3. Participant opens the app and is prompted to scan the QR code
4. Participant receives push notifications when they need to complete a task
5. When the study is completed, the participant uninstalls the MyCap app from their device (or, if participating in multiple MyCap projects, [deletes the project from their MyCap app](#))

Participant parameters

MyCap can only work with one participant per device. Meaning, if you have a project where multiple people in a household might participate, each one of those people will need to use a separate device from the other participants in the household. You can't download the MyCap app, for instance, and create multiple profiles within the App for each family member. This is a limitation the developer is working on.

Additionally, each participant has to use only one device when reporting through MyCap. Say a participant has a cell phone and a tablet. Whichever device they use sends task results to the server. The server does not send task results to the device. The participant's tablet will have no knowledge of a task that was completed on the phone. If a participant were to get a different device, however the user could have the task results sent from the server to the participant's new device. It's just not something you would want to do on a continuous basis.

Multiple MyCap project participants

Participants can switch between projects if they are participating in multiple projects.

Communication with Participants

The research team can communicate with the study participant via secure text messaging system at no cost.

MyCap uses its internal messaging system. It is not using a third-party service. There are no data charges. When using this feature, the participant will see the message 'You have a secure message waiting' displayed. When the participant clicks on that push notification, MyCap calls REDCap database for the message.

Please note that if the participant messages the researcher, the researcher will not receive a notification about a waiting message.

Project Creation

REDCap administrators can create new projects compatible with MyCap. REDCap end users cannot set up MyCap without help from an administrator.

Currently only classic REDCap projects are supported. Longitudinal projects are not compatible at this point. If you have an existing longitudinal project, it is recommended that you make a companion classic project for MyCap.

Enabling MyCap on an existing project

MyCap can be enabled on existing classic REDCap projects but there are several actions that need to be performed manually. It is therefore recommended that the REDCap administrator create a new project for MyCap. If you, the end user, have existing forms you have already made, you can export and import them into your new MyCap project.

User permissions specific to MyCap projects

The MyCap external module uses REDCap's user permissions to determine who is allowed to do what. This means that whichever permissions you are assigned as a user on the REDCap project will determine which of these MyCap rights you have.

Role	MyCap Rights	REDCap Project Permission
Admin	<i>Designer</i> + Manage Projects, Settings, anything in the administration area	REDCap administrators are given the MyCap Admin role
Designer	<i>Basic</i> + Configure App (Tasks, Theme, Contacts, etc...)	REDCap users with "Project Design and Setup"
Basic	View Dashboard, Read Help, Create Messages & Announcements, Manage Participants	REDCap users with "View and Edit, Data Entry Rights"
None	None	Anything else

MyCap design

You will define what datapoints you want to collect in your REDCap project. The MyCap interface specifies when the instruments should be completed by participants.

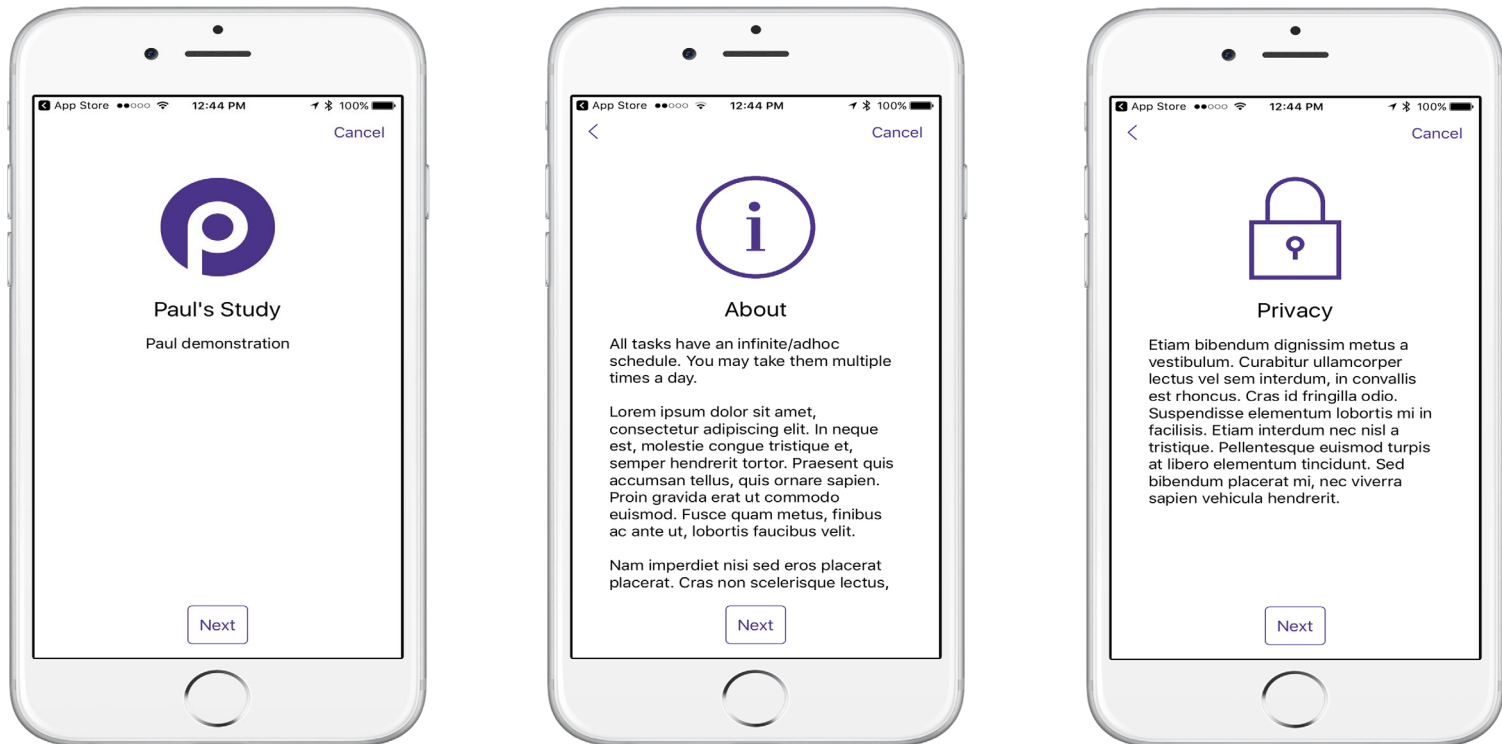
Custom Themes

There are pre-set color themes that come with the MyCap interface in the iOS (iPad/iPhone) version. You can select the one that appeals to you.

Introductory Screens

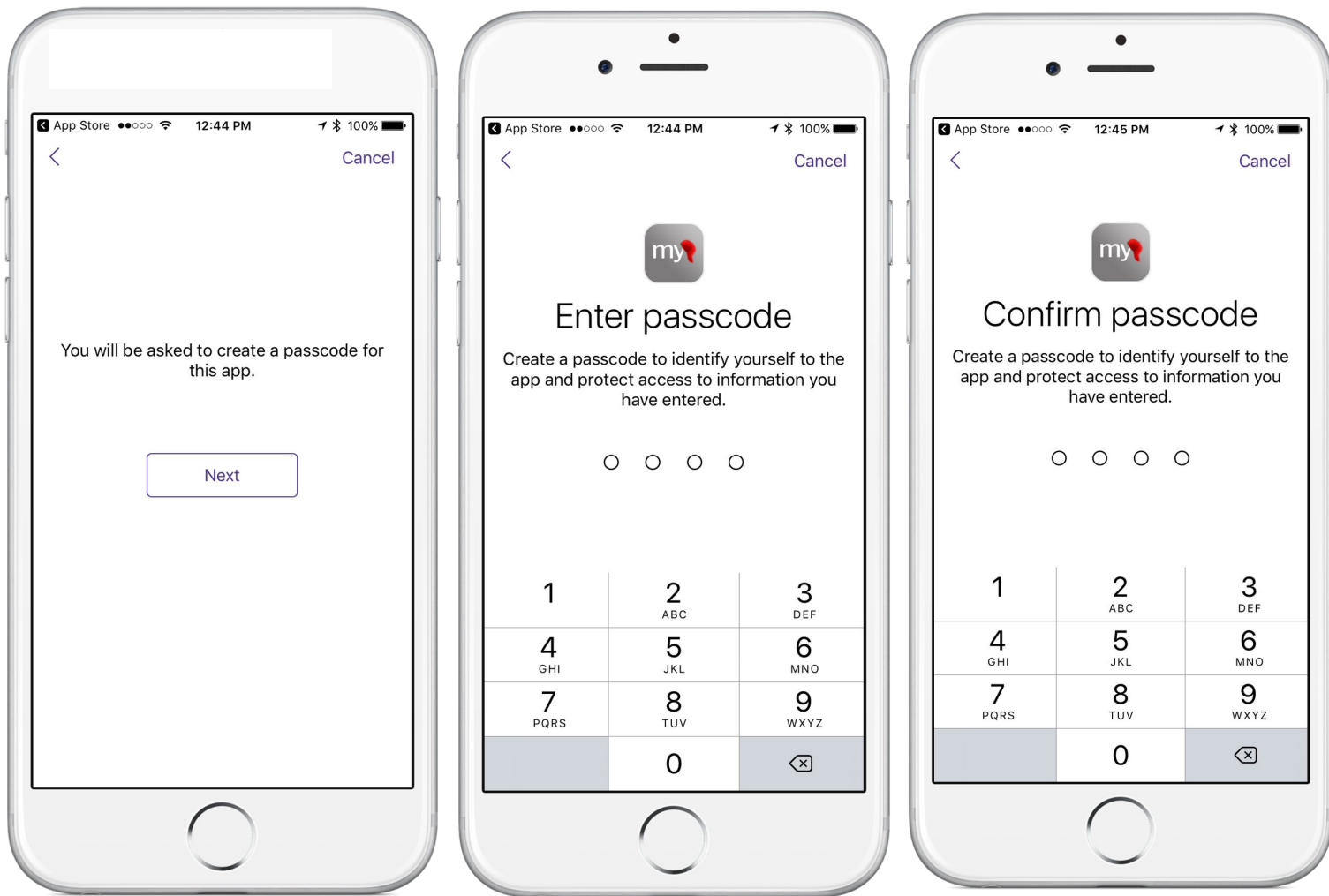
There are several introductory screens that you can elect to have for the project:

Project-Specific Introduction Screens

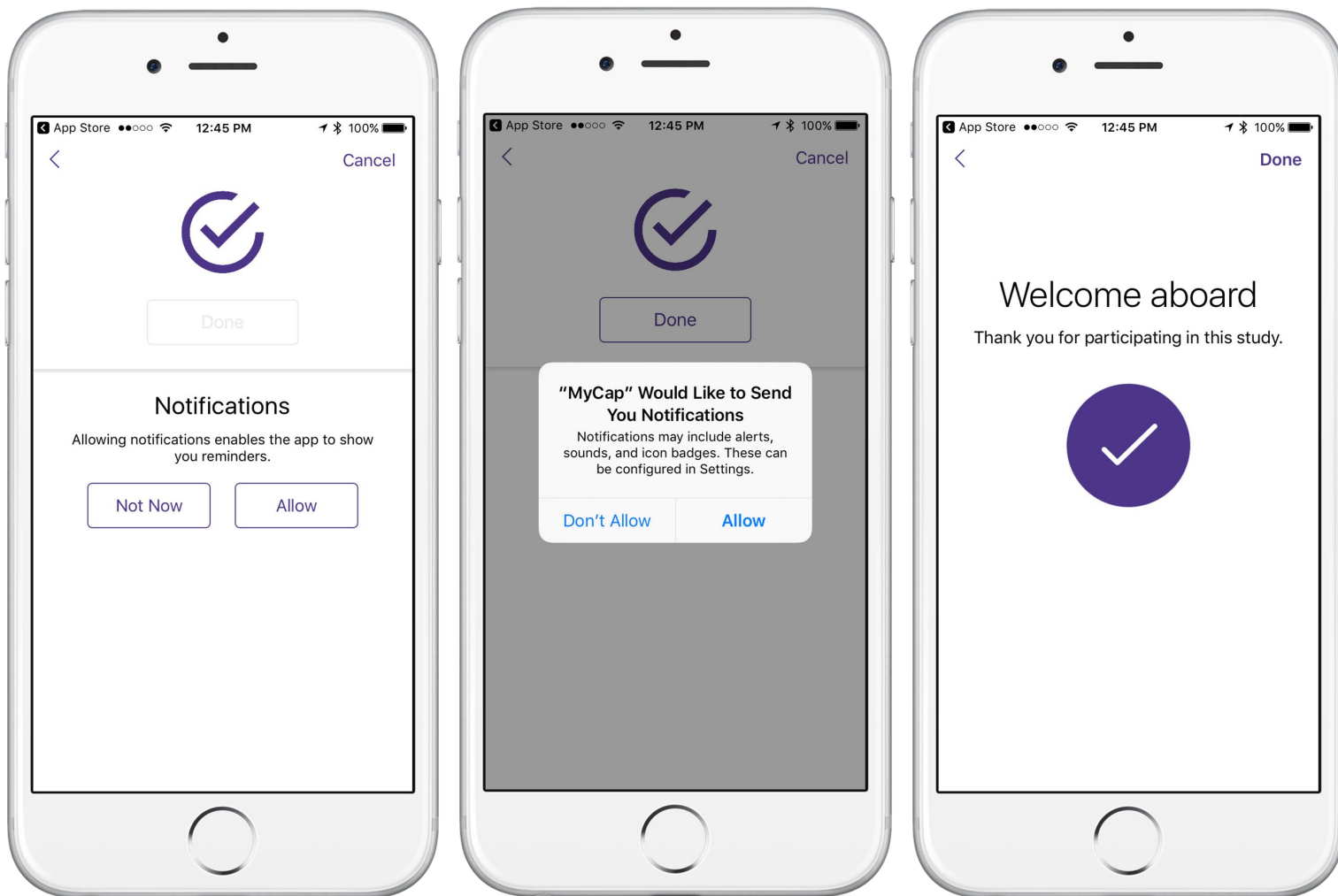


Security Screens

The study participant will create a passcode to identify themselves to the app and protect access to information already entered. The passcode is a 6 digit number.



Permissions Screens



Project Design specific to MyCap projects

Features Supported/Unsupported in MyCap

- Piping is not currently supported in MyCap.
- Smart variables are not supported in MyCap.
- Single-statement ([foo] = 1) branching logic has always been supported. Complex branching logic ([foo] = 1 AND ([bar] > 2 OR [baz] = 'Hello')) is available since MyCap Android v1.5.1 and iOS v2.5.0. However, mathematical functions "([foo] > ROUND(2.5))" are not supported.
- In a traditional REDCap project, a user can assign project users to Data Access Groups (DAGs) to limit which records the user sees. In a MyCap project, the list of contacts appears for all users so there is no way to limit which records a user sees.

Fields Supported/Unsupported in MyCap

Type	Validation	Supported	Notes
Text Box (short text, number, date/time, ...)	Date (DMY) Date (MDY) Date (YMD) Datetime (DMY HM) Datetime (MDY HM) Datetime (YMD HM) Datetime (DMY HMS) Datetime (MDY HMS) Datetime (YMD HMS) Email Integer Number Phone (North America) Zipcode (US) Time (HM)	Yes Minimum and maximum time values not yet supported	Minimum and maximum date range values not yet supported for all 9 date formats
Notes Box (paragraph text)		Yes	
Calculated field		No	
Multiple choice	Drop down Radio button Checkboxes	Yes	
Yes/no – True/false		yes	
Signature		no	
File upload		Yes	The file upload field is used to capture images and video. See annotations: *@MC-FIELD-FILE-IMAGECAPTURE and

			@MC-FIELD-FILE-VIDEOCAPTURE
SLIDER/Visual Analog Scale		Yes	See annotations: @MC-FIELD-SLIDER-BASIC and @MC-FIELD-SLIDER-CONTINUOUS
Descriptive Text		No	
Matrix of fields		No	

Task & Active Task

You have the ability to schedule tasks and active tasks for your participants. The term task comes from ResearchKit. You can think of a task in the MyCap app as being a survey in a REDCap project.

Active Tasks

Active tasks are ones that participants perform using sensor on the mobile device (touch display, accelerometer, etc) to capture data. The ability to capture active tasks is due to third party programmers who develop the code and add it to an open-source project, which MyCap downloads. Tasks can be developed for iOS (via ResearchKit), Android (via ResearchStack) or both. Android only has a few.

Note that most MyCap projects don't use Active Tasks, so it is still completely feasible to use MyCap even if you don't plan on taking advantage of that feature.

On the following pages are some examples of active tasks.

Active tasks in ResearchKit (for iOS devices)

CATEGORY	TASK	SENSOR	DATA COLLECTED
Motor Activities	Range of Motion	Accelerometer Gyroscope	Device motion
	Gait and Balance	Accelerometer Gyroscope	Device motion Pedometer
	Tapping Speed	Multi-Touch display Accelerometer (optional)	Touch activity
Fitness	Fitness	GPS Gyroscope	Device motion Pedometer Location Heart rate
	Timed Walk	GPS Gyroscope	Device motion Pedometer Location
Cognition	Spatial Memory	Multi-Touch display Accelerometer (optional)	Touch activity Correct answer Actual sequences
	Stroop Test	Multi-Touch display	Actual color Actual text User selection Completion time
	Trail Making Test	Multi-Touch display	Completion time Touch activity
	Paced Serial Addition Test (PSAT)	Multi-Touch display	Addition results from user
	Tower of Hanoi	Multi-Touch display	Every move taken by the user
	Reaction Time	Accelerometer	Device motion

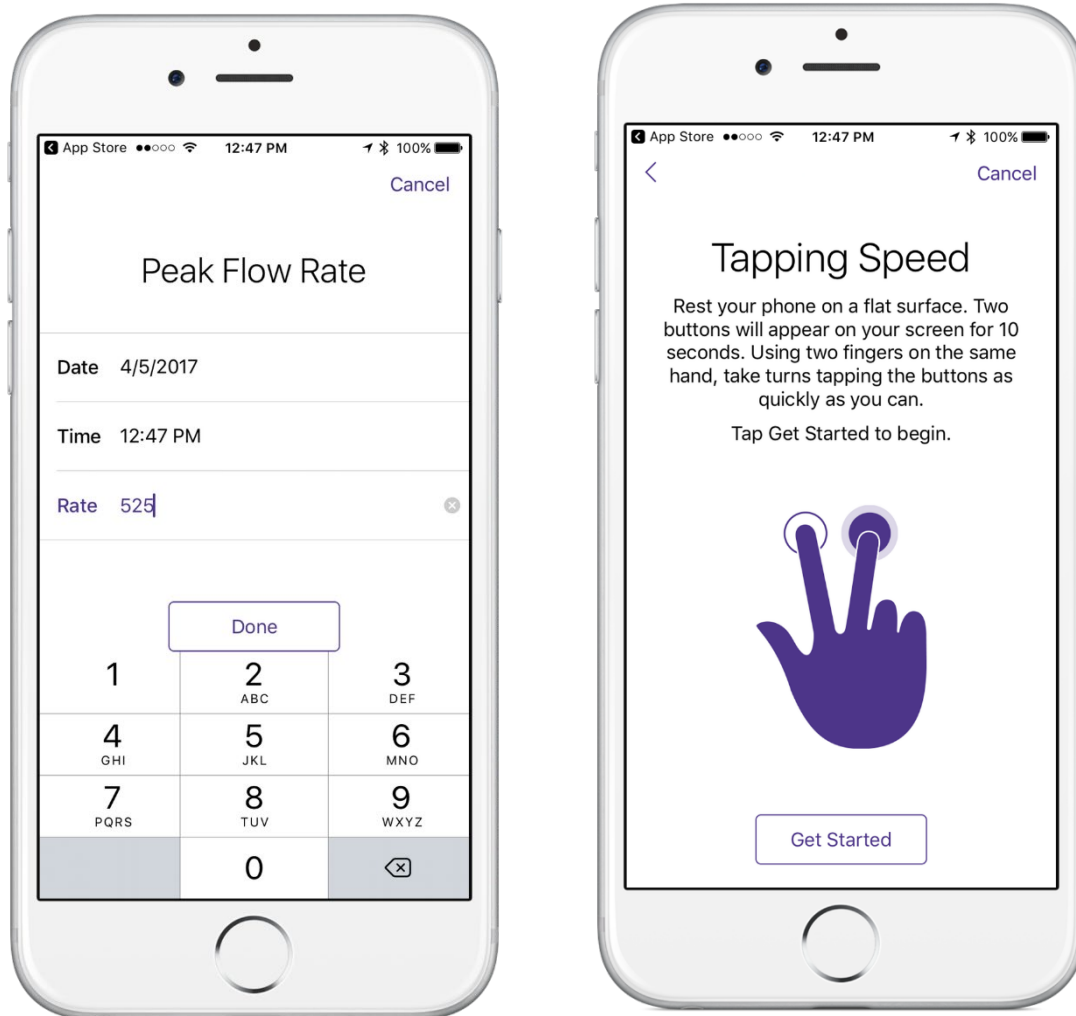
Active tasks in ResearchKit (for iOS devices)

CATEGORY	TASK	SENSOR	DATA COLLECTED
		Gyroscope	
Speech	Sustained Phonation	Microphone	Uncompressed audio
	Speech Recognition	Microphone	Raw audio recording Transcription in the form of an SFTranscription object. Edited transcript (if any, by the user)
	Speech-in-Noise	Microphone	Raw audio recording Transcription in the form of an SFTranscription object Edited transcript (if any, by the user). This can be used to calculate the Speech Reception Threshold (SRT) for a user.
Hearing	Environment SPL	Microphone	Environment sound pressure level in dBA
	Tone Audiometry	AirPods Headphones	Minimum amplitude for the user to recognize the sound
	dBHL Tone Audiometry	AirPods Headphones	Hearing threshold in dB HL scale User response timestamps
Hand Dexterity	9-Hole Peg	Multi-Touch display	Completion time Move distance
Vision	Amsler Grid	Multi-Touch display	Touch activity Eye side Areas of distortions as annotated by the user

For more information see <http://researchkit.org/docs/docs/ActiveTasks/ActiveTasks.html>

For information on ResearchStack (for Android devices) see <http://researchstack.org/>

Active Task Examples



Scheduling Tasks

A task can be scheduled relative to an Install Date or Baseline Date.

Install Date

The date a participant scanned the QR code to load your project. This is automatically set by MyCap.

Baseline Date

Some projects schedule tasks relative to a baseline date. For example, the baseline date in a physical therapy project might indicate the date the participant began physical therapy. A participant may install MyCap and scan the QR code on 2017-01-01, but may begin therapy on 2017-01-20. If you want a daily diary task to appear after 2017-01-20, turn the 'Use Baseline Date?' setting ON.

QR Codes explained

Anatomy of a QR code

You will need to generate a QR code for each study participant.

```
1 {  
2   "endpoint": "http://localredcap:9001/api/?type=module&prefix=mycap&page=web%2Fapi%2Findex&NOAUTH",  
3   "studyCode": "P-NPGKZ6PCPBBNYLFFD1A6",  
4   "participantCode": "U-HMNEUN9ZC6M7BG44D94P"  
5 }
```

Anatomy of a QR code:

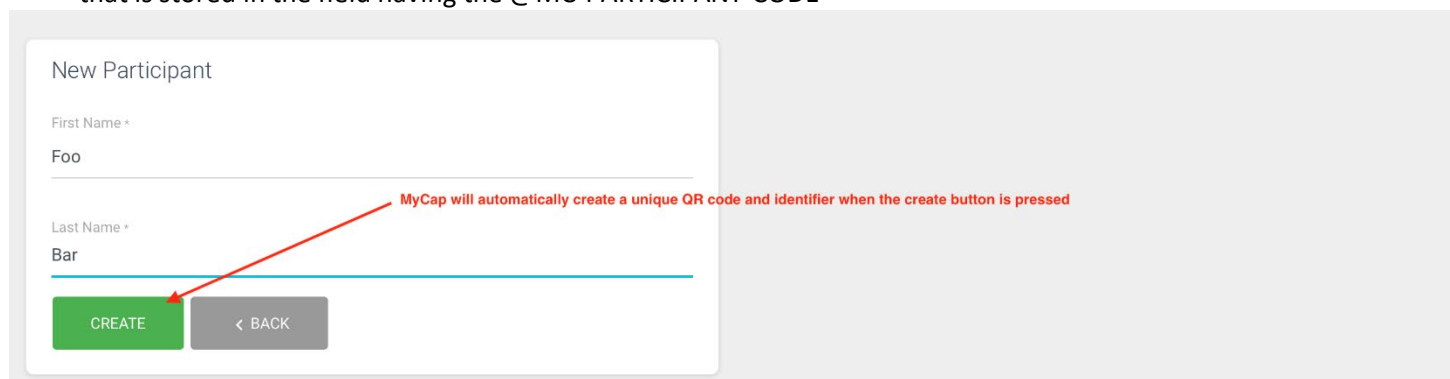
- 1) "endpoint" = which REDCap server to speak to
- 2) "studyCode" = a unique identifier for the project. An alias for a REDCap PID
- 3) "participantCode" = a unique identifier for the participant. An alias for a record ID. See the @MC-PARTICIPANT-CODE annotation



Generating a QR code for a participant

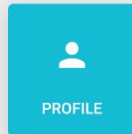
There are several different ways you can generate a QR code for a participant. Here are some options:

1. Let the MyCap module create a new participant (REDCap record) and automatically generate a unique identifier that is stored in the field having the @MC-PARTICIPANT-CODE



2. Use REDCap to create a new participant record. Then click the "Generate" button within the MyCap module to create a unique participant code

Created Via REDCap Interface



MESSAGES

Edit Participant

First Name *

Created

Last Name *

Via REDCap Interface

Install Date

Baseline Date

SAVE

< BACK

Participant QR Code

The participant record was created using REDCap's interface. Researcher must press the generate button to create a unique identifier for this participant.

GENERATE

3. Use REDCap to create a new participant record. Enter a unique value into the field having the @MC-PARTICIPANT-CODE annotation. MyCap will not prompt you to generate a code because there is already a value.

Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: Text Box (Short Text, Number, Date/Time, ...)

Field Label ☐ Use the Rich Text Editor ?

Code

The first form contains a field with the @MC-PARTICIPANT-CODE annotation. This unique participant code is use when generating a MyCap QR code. A researcher can either let MyCap generate these unique codes or use their own custom naming scheme. Note that the codes should be unique and non-guessable... so never use sequential numbers without additional complexity.

Action Tags / Field Annotation (optional)

@MC-PARTICIPANT-CODE @HIDDEN

Learn about [@ Action Tags](#) or [using Field Annotation](#)

Variable Name (utilized in logic, calcs, and exports)

par_code ☐ Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

How to use [Smart Variables](#) [Piping](#) [Field Embedding](#)

Validation? (optional) ---- None ----

-- OR --

-- select ontology service --

Required?* ☒ No ☐ Yes

* Prompt if field is blank

Identifier? ☒ No ☐ Yes

Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment Right / Vertical (RV)

Align the position of the field on the page

Field Note (optional)

Small reminder text displayed underneath field

Save Cancel

Distributing a QR code to a participant

There are several different ways you can distribute a QR code to a participant. Here are some options:

1. Take a screenshot of the QR code and email to a participant
2. A coordinator may help direct the participant to download the MyCap and scan the QR code in person if the participant is visiting a clinic
3. Print the QR code onto paper and mail to a participant
4. Use REDCap's Alerts & Notifications feature to automatically email a QR code to a participant. Use REDCap's piping mechanism to pipe the participants @MC-PARTICIPANT-CODE value into the contents of the QR code. This requires understanding of the QR code contents. Use a QR code reader on an existing QR code to see the correct format.
5. Enroll participants using a survey. Use the survey feature to automatically redirect a participant to a web page you create that is responsible for displaying QR codes. See Demo #1 on <https://www.projectmycap.org> for an example of this. Requires custom programming and the REDCap API.

Participant removal

Participant removal from a study

If a participant is only participating in a single project and they want to leave the project, then they can simply uninstall the MyCap app.

Removing oneself from the MyCap app or deleting the MyCap app entirely only deletes data on the participants device. No previously transmitted data will be deleted from the REDCap project.

Participant removal from a specific MyCap project

- On Android, tap the "Project" tab at the bottom of the screen and tap the "Delete" menu option.
- On iOS, tap the menu icon in the top-left of the screen and then tap the "Delete" menu option.

This will delete the MyCap project from the MyCap app. This is typically only useful if a participant is participating in multiple MyCap projects and one of them has ended.

Consenting participants

Consenting of participants needs to be done outside of MyCap.

Viewing collected data

To view the data entered by your study participants, you will simply go to your REDCap project and use the data viewing tools there, as you normally would.

Example MyCap projects

Below are some examples of how MyCap has been used in real life.

Tablets pre-loaded with MyCap

There have been projects where a user will pre-load a tablet with MyCap for a specific participant and mail the tablet to the participant. The participant can then respond to the tasks and upon study completion, mail the tablet back to the user. When the tablet is in transit, it is in offline mode. See more about that [in this section of this document](#).

Operational use

Teachers log in on a daily basis and answer questions about their students. So instead of the teacher having to check their

inbox and click on the survey link, they just open the app and enter their information there.

COVID research case

A school in Nashville used MyCap for a COVID research study. Participants (students, faculty and staff of the school) completed eConsent via REDCap survey. An alert email automatically emailed the QR code to the participant. The participant then downloaded the MyCap app and scanned the QR code. After this set up, there was a weekday collection process during which the participant would:

1. Spit into a tube provided to them by the school.
2. Scan the barcode on the tube using the MyCap app.
 - a. The camera on the cell phone is used to point at the bar code on the test tube.
3. Answer questions (COVID safety questions like “Did you wear your mask all the time?”)
4. On the same day, after they’ve submitted their task in MyCap, they drop off their tube at a central location at the school.

After the participant submits their response:

1. The response is sent to the REDCap project.
2. Tubes are collected from the school and delivered to a lab.
3. The lab analyzes the samples.
4. The lab creates a report in a csv file which ties the results (positive, negative, unclear) to each barcode.
5. The lab tech uploads the csv file to the REDCap project File Repository.
6. A custom external module processes the result file, matching the csv file results with the REDCap instance. It then messages negative results to participants via MyCap. Positive result participants are notified by a school nurse.

To demo MyCap

To try out MyCap, you can go to <https://projectmycap.org/> and scroll down to the ‘Try It Out’ section. You’ll find demonstration opportunities for basic functionality, active tasks and scheduling.

Appendix

Deciding which platform to use

Compare and Contrast: MyCap vs REDCap Mobile app vs. traditional REDCap project

Need	MyCap	REDCap Mobile app	Trad. REDCap project
Longitudinal data collection	Not available	Available	Available
Offline data collection	Available	Available	N/A
Single survey completed once	Not optimal	Reasonable	Reasonable
Information entered by study participant	Yes	No (although, study team member could hand device to participant)	Yes
Send secure notification	Available	Not available	Not available
Study info easily accessible by study participant	Feasible	Not feasible	Not feasible
Study participants not known in advance	Not feasible	Feasible	Feasible

MyCap vs. traditional REDCap project

MyCap is designed for studies where participants are completing tasks on a regular basis (daily/weekly/monthly), offering advantages over distributing surveys from a traditional REDCap project such as:

- Participants can be notified automatically with push notifications vs. having to check their email and click on a link.
- MyCap gives the study team a way to provide participants with easy access to information such as support phone numbers and contacts at any time, simply by opening the app.
- Send a secure text announcement
 - To all participants in a project. For example, periodically send messages about news related to the study
 - To a single participant. Similar to sending an email to an individual person but more secure. This can be anything such as ‘you have an appointment soon’ or ‘Great job, you are 50% complete with the study’
- An external links mechanism lets a researcher display any external webpage easily within the MyCap app. You can link to educational resources, videos, custom participant dashboards, etc.

When MyCap is not recommended

MyCap is not a module suitable for all studies. For example, the traditional REDCap project would work best if:

- Your project is something simple like a survey that goes out 1 or 2 times a year (it would be more practical to use a simple REDCap project)
- You do not have a pre-identified set of participants (in other words, if you would post your public survey link on a website for anyone to fill out)
- Your project is longitudinal and cannot be easily converted to a classic project

IRB Approval

The MyCap application by itself is within a category of devices the FDA has indicated will not be regulated as a medical device or as mobile medical application at this time. The law (1976 Medical Device Amendments) defines the term device. However, it is often the intended use of the device that will affect the determination of a FDA regulated “medical device.” If the intended use of a device such as MyCap, or set of devices including MyCap, is for diagnosing disease or other conditions, or is used for cure or mitigation, treatment or prevention of disease, or is intended to affect the structure of man, the device(s) may be determined to be a FDA regulated medical device(s).

Please consult your institution’s regulatory board (IRB) or regulatory group if you have any concerns.

Technology

MyCap leverages REDCap, ResearchKit, and ResearchStack to capture participant/patient reported outcomes via mobile devices. REDCap is used to define tasks/instruments/surveys to be completed by participants. MyCap translates REDCap task metadata into a structure compatible with [ResearchKit](#) and [ResearchStack](#). When a project participant completes a task, MyCap converts the results into a format compatible with REDCap before synchronizing back to the REDCap project.

Internet requirements

Data entry can take place with or without Internet connection, although Internet connection is required for data to be transferred to and saved on the server. In addition, a participant will need to have internet access to download the MyCap app and scan their QR code so they can load the project on their mobile device.

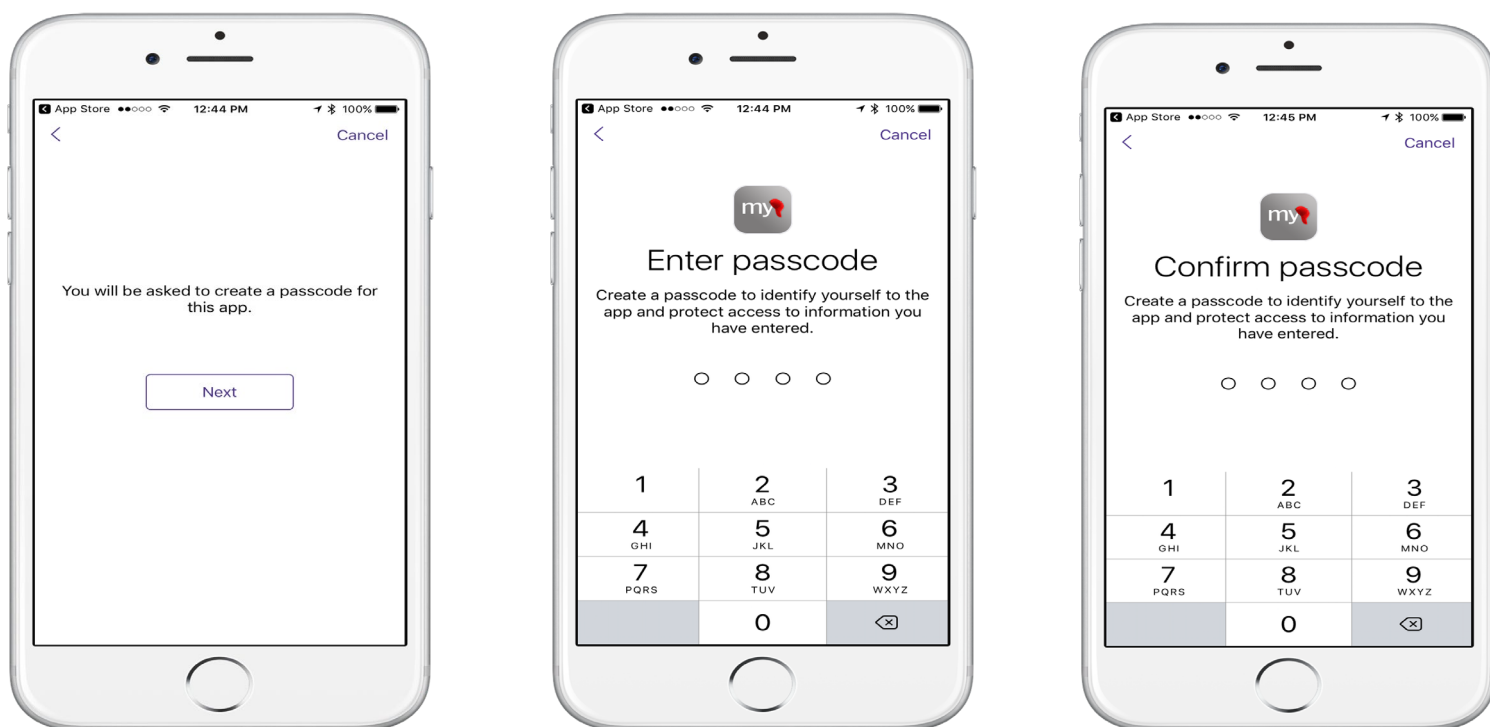
Offline Capabilities

After installing the app, the participant can use it in offline mode (e.g. they can still use it when they have not

internet/wifi). Data collected while offline is stored in an encrypted database on the device. Once the participant gets internet access back, data is synced back to the REDCap server.

Security features of MyCap

- Participant data are stored locally on the device in an AES-256+SHA2 encrypted database. Data remains on the device if an internet connection is not available. Applies to both iOS and Android devices.
- When an internet connection is available, data are transmitted directly to REDCap using a SSL (TLS v1.2) connection. A hash-based message authentication code (HMAC) is used to verify the integrity of the data and to authenticate the sender.
- Participant entered data (i.e. task responses) are not stored or sent anywhere else. Data exists on the participant's device or on your server.
- Data are wiped from the device after the MyCap app verifies that data have been successfully transmitted. Note that there is an optional MyCap feature that lets a participant see some of the data they entered for an individual task/instrument/survey. By default, data are wiped.
- Participants create a 6-digit PIN that is used to open the app. A participant can disable the PIN feature.



MyCap and 3rd party services

The MyCap mobile app uses Firebase Analytics, Crashlytics, and Cloud Messaging. Firebase generates its own identifiers that live on the participant's device. There is no way for Vanderbilt to link a MyCap participant code to a Firebase user identifier. Participant meta-data stored in Firebase cannot be linked to participants in your project.

Messages sent to and from a participant are transmitted via the MyCap API, not Cloud Messaging. Cloud Messaging simply handles push notifications, and the push notification message is always "You have a secure message waiting."

