Mass General Brigham

HUMAN RESEARCH AFFAIRS

MyCap IRB Submission and FAQs

MyCap:

MyCap, a new feature now available in REDCap is a customizable participant-facing mobile application (app) that captures patient reported outcomes based on a REDCap project. MyCap collects data through surveys and the automated administration of active tasks (activities performed by participants using mobile device sensors under semi-controlled conditions) from any mobile device (iOS or Android).

Researchers can distribute a QR code or hyperlink in relation to the REDCap MyCap project using any of the currently available methods in REDCap (e.g., displayed to participants after they complete a survey, sent via email). Details on MyCap QR code/link distribution can be found here. If participants do not currently have the app installed on their devices, they will be brought to their respective app store to download the app. The MyCap App can also be used for offline participant data collection, and all data collected are automatically sent back to the REDCap server as soon as an internet connection is available. This app makes it simple and inexpensive (no-cost) for researchers to use a mobile app to capture participant reported outcomes on both iOS and Android devices. MyCap provides a quick two-way messaging system between REDCap and the participant's MyCap app (e.g., messaging and announcements).

If you would like to use MyCap in your research, be sure to include its use in your protocol for new studies or submit an amendment for ongoing studies to the IRB along with a revised consent form and protocol incorporating the language described below. Include information in the amendment form about how you will use MyCap in your study.

MyCap Consent or Information Sheet Language:

In this study, we will collect data using a mobile application called MyCap. This app will need to be downloaded to your mobile device (iOS or Android). All data collected in the MyCap app is automatically sent back to the system where the research team stores data. Data collected via MyCap will live on your device or in the research system, and it will not be sent to third parties. Data charges may apply when using MyCap as this app requires internet connection to send and receive data. You can send messages to the research team via the MyCap app. Do not use MyCap to send messages for urgent contact. Contact the study team directly using the information provided to you in the consent form for emergencies. We will use this app to: *Add information about how you will use MyCap in this study* (e.g., send you push notifications and reminders to complete tasks related to participation in this study. The tasks that you will complete include: *provide a description*)

Instructions to Investigators: *In the consent, in addition to the above describe how participants will use MyCap in your study (e.g., how you will send the QR code or hyperlink for participants to download the app, what activities will participants complete via the app, who will be responsible for the data charges)*:

MyCap Protocol Language:

This study will be using a mobile application called MyCap that will need to be downloaded to a participant's mobile device (iOS or Android). We will use this app to: *Add information about how you will use MyCap in this study including:*

- Use of push notifications and reminders to complete tasks related to participation in this study.) The
- Surveys/questionnaires used, and the following
- Names of specific active tasks that will be used

Instructions to Investigators: *The protocol should describe how MyCap will be used, the type of data that will be collected, the tasks that will be completed by participants.*

Digital Health Form:

The Digital Health form in the Insight application should be completed as follows:

Section	Question	Answer
Digital Health Technology	Will you be using mobile and wireless devices, wearable devices, smartphone apps, digital health tools, health-related IT, new healthcare software and related new technologies to generate, use and/or disseminate health information or physiological data? Note: Wearable devices can include activity trackers (i.e., FitBit), free-standing monitors or sensors worn on body which connect through wireless, Bluetooth or other method to passively collect data.	Yes
	Indicate type of digital health technology being used in the study (check all that apply):	Smartphone application
	List name and manufacturer of each "digital health" technology that will be used in the study. You will be asked to complete questions for each "digital health" technology listed.	MyCap, part of MGB REDCap implementation
Web-based Data	Will you be using web-based survey or data collection tools to administer a survey or questionnaire?	Yes: *Then Choose:*

Version: 2024.06.20

Collection Tools		Survey / Data collection tool hosted inside Mass General Brigham firewall. *Then Choose:* REDCap or StudyTRAX through Mass General Brigham

The above information should be included in your IRB submission if you are requesting to use MyCap at the time of Initial Review or should be revised for ongoing studies via an Amendment.

For questions about creating a MyCap project, contact the REDCap team: redcap@mgb.org or visit the REDCap Resource Center at this link.

MyCap FAQ for Investigators

1. What is MyCap?

MyCap, a feature of REDCap is a freely available participant-facing mobile application that can be installed on iOS and Android devices to capture patient-reported outcomes for any REDCap project.

2. How does the data from the app get sent to REDCap?

All data completed on a participant's device are automatically and immediately synchronized to REDCap. If data are completed while participants are offline, data are synchronized when internet connect is restored and the App is opened. All MyCap data is sent directly via an API call to the MGB REDCap server. Sent data is associated with a specific project and record. Data is not sent to third parties.

3. How do I modify my existing studies to request the use of MyCap?

If you would like to use MyCap in your research, submit an amendment to the IRB along with a revised consent form and protocol incorporating the language described below. Include information in the amendment form about how you will use MyCap in your study.

MyCap Consent Language:

In this study, we will collect data using a mobile application called MyCap. This app will need to be downloaded to your mobile device (iOS or Android). All data collected in the MyCap app is automatically sent back to the system where the research team stores data. Data collected via

3

MyCap will live on your device or on in the research system, and it will not be sent to third parties. Data charges may apply when using MyCap as this app requires internet connection to send and receive data. You can send messages to the research team via the MyCap app. Do not use MyCap to send messages for urgent contact. Contact the study team directly using the information provided to you in the consent form for emergencies. We will use this app to: *Add information about how you will use MyCap in this study* (e.g., send you push notifications and reminders to complete tasks related to participation in this study. The tasks that you will complete include: *provide a description*)

Instructions to Investigators: In the consent, in addition to the above describe how participants will use MyCap in your study (e.g., how you will send the QR code or hyperlink for participants to download the app, what activities will participants complete via the app, who will be responsible for the data charges):

MyCap Protocol Language:

This study will be using a mobile application called MyCap that will need to be downloaded to a participant's mobile device (iOS or Android). We will use this app to: *Add information about how you will use MyCap in this study including*

- Use of push notifications and reminders to complete tasks related to participation in this study.) The
- Surveys/questionnaires used, and the following
- Names of specific active tasks that will be used

Instructions to Investigators: The protocol should describe how MyCap will be used, the type of data that will be collected, the tasks that will be completed by participants.

Digital Health Form:

The Digital Health form in the Insight application should be completed as follows:

Section	Question	Answer
Digital Health Technology	Will you be using mobile and wireless devices, wearable devices, smartphone apps, digital health tools, health-related IT, new healthcare software and related new technologies to generate, use and/or disseminate health information or physiological data? Note: Wearable devices can include activity trackers (i.e., FitBit), free-standing monitors or sensors worn on body which connect through wireless, Bluetooth or other method to passively collect data.	Yes
	Indicate type of digital health technology being used in the study (check all that apply):	Smartphone application

	List name and manufacturer of each "digital health" technology that will be used in the study. You will be asked to complete questions for each "digital health" technology listed.	MyCap, part of MGB REDCap implementation
Web-based Data Collection Tools	Will you be using <u>web-based</u> survey or data collection tools to administer a survey or questionnaire?	Yes: *Then Choose:* Survey / Data collection tool hosted inside Mass General Brigham firewall. *Then Choose:* REDCap or StudyTRAX through Mass General Brigham

The above information should be included in your IRB submission if you are requesting to use MyCap at the time of Initial Review or should be revised for ongoing studies via an Amendment.

For questions about creating a MyCap project, contact the REDCap team: redcap@mgb.org or visit the REDCap Resource Center at this link.

4. **I am working on a new study and would like to request the use of MyCap. What do I submit to the IRB?**

   Refer to the information in # 3 above.

5. **Who do I contact for technical questions about MyCap?**

   For questions about creating a MyCap project, contact the REDCap team: redcap@mgb.org or visit the REDCap Resource Center at this link.

6. **What time stamps are logged for activities when a participant completes a survey offline (completion date/time) versus when the survey is actually transmitted (transmission date/time)..**

   Every REDCap instrument that has been activated as a MyCap task has a number of required fields that are automatically added if not already present. Two of these are "task start" and "task end". These fields automatically capture the time/date a task was started and completed on the users' device. This is in addition to the logging REDCap already records for record creation/update/deletion. Additionally, MyCap captures a sync date to record when the data was uploaded to the REDCap server.

7. What user IDs are associated with entries?

These IDs are a combination of researcher defined and REDCap/MyCap defined: A researcher adds a record into a REDCap project for each participant. That record has a unique record ID. All activity including data entry is recorded in the project log associated with this record ID. In addition, MyCap assigns a random, anonymous participant identifier (@MC-PARTICIPANT-CODE) to each participant, which is required to ensure responses get tied to the correct record. This value is stored on every record in a MyCap enabled project. Each database entry (task completed) is automatically given a 36-character universally unique Identifier (UUID). This value is stored as a field in each MyCap enabled instrument.

In MyCap, the account name/ PIN number created by a participant is stored locally on their device and not shared with researchers or sent back to MGB REDCap. No user IDs made by MyCap participants are saved to the MGB REDCap project.

8. If an entry is changed (by staff or by participant), how is that reflected in the audit trail?

If any data is changed or modified by a researcher in REDCap, the activity and user who made this modification is stored in the REDCap project logs and associated with MGB/REDCap username, the same as current REDCap projects. When a MyCap participant enters/syncs data, the REDCap logging displays: startdate, enddate, uuid, and device uuid captured in mandatory fields as well as the data field updates.

9. When someone completes a survey, does the data go directly to the study team's project in REDCap?

All MyCap data is sent directly via an API call (Vanderbilt supported integration) to the MGB REDCap server. Sent data is associated with a specific project and record. Data is not sent to third parties.

10. Are there any potential charges to the participant's phone plan for use of the app (data costs, messaging etc.)?

Data charges may apply. The MyCap app requires internet connection to send and receive data, so any use of the app would require the device owner to have a funded data plan or to use a wifi data connection.

11. What are the requirements with regard to space on the person's phone for downloading the app?

The app currently has a size of 248mb for Android devices and 279mb for iOS.

12. Is there a user agreement that the participant must sign?

No specific end-user agreement is required to use the app. A MyCap privacy policy is provided within the app. Participants do not need to attest or confirm receipt of privacy policy.
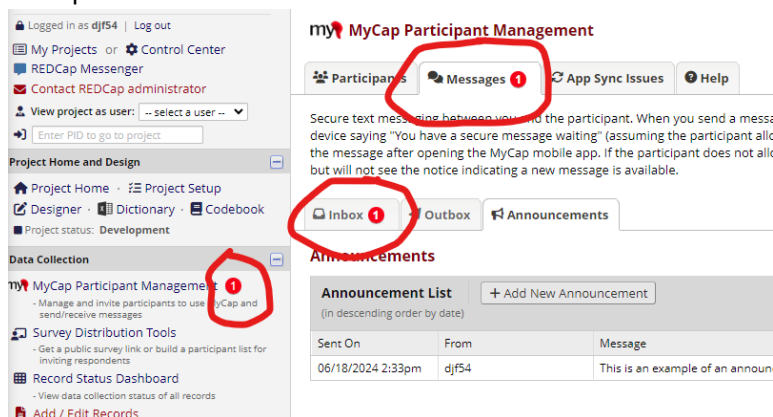
13. What are the full range of uses of the app for research?

The MyCap is best utilized for research projects that require routine or repeated data collection by a study participant. This may come in the form of fully remote trials, decentralized trials, or hybrid trials where MyCap augments in person visits. The MyCap Use Cases page on the website (https://projectmycap.org/mycap-use-cases/) outlines specific uses for medication adherence, program delivery/adherence, post op monitoring follow up, remote patient monitoring, surveillance studies, COVID studies, exercise tracking, etc.

14. How are messages sent by participants via the MyCap app received by the study team? Do they go to a central messaging location, a particular person?

Any message sent via the MyCap app is shown to the researcher in the REDCap project's "MyCap Participant Management" section of the tool. When a message is sent from the participant to the researcher, there's a visual indicator on the MyCap Participant Management screen, as well as the "Messages" tab.

Example:

For the researcher, messages can be sent to the entire cohort or to individual participants.

15. How will the research team know if there is a message that needs to be acted upon immediately?

Researchers must check the notifications in the project every day and review. Study teams will need to set up internal processes/SOPs to ensure that notifications are reviewed at least daily when MyCap is used.

16. How do the participants download the app? Does the study team have to send them a link, QR code, etc.?

Researchers can distribute a QR code or hyperlink in relation to the REDCap MyCap project using any of the currently available methods in REDCap (e.g., displayed to participants after they complete a survey, sent via email). Details on MyCap QR code/link distribution can be found here. If the participants do not currently have the app installed on their devices, they will be brought to their respective app store to download the app.

17. Since data (including PHI) could be stored on the person's phone until they have a connection to transmit, what are the security requirements for the user's phone? Will participant phones require password protection?

MyCap does not modify the security settings on individual devices. When a participant installs the app, they are instructed to create a profile and are given the option of setting a PIN number associated with this profile.

Template Development Support:

MyCap example use cases: https://projectmycap.org/mycap-use-cases/

MyCap decision tree: https://projectmycap.org/wp-content/uploads/2021/06/MyCapDecisionTree.pdf

MyCap white paper: https://academic.oup.com/jamiaopen/article/5/2/ooac047/6601324?login=false

MyCap informative video: https://www.youtube.com/watch?v=unyWcEDip0Y

1. **What is MyCap?**

    MyCap is a freely available participant-facing mobile application that can be installed on iOS and Android devices to capture data for research studies.

2. **How do I download MyCap?**

    Researchers will share a QR code or hyperlink with you. If you do not currently have the app installed on your device, you will be brought to "app store" on your phone to download the app.

3. **Can I send a message to the research team via MyCap?**

    Yes, you can send messages to the research team via the MyCap app. Do not use MyCap to send messages for urgent contact. Contact the study team directly using the information provided to you in the consent form for emergencies.

4. **Are there any potential charges to my phone plan for use of the app (data costs, messaging etc.)**

    Data charges may apply. The MyCap app requires internet connection to send and receive data, so any use of the app would require the device owner to have a funded data plan or to use a wifi data connection.