



SOP.POINT01.01
POINT App User Guide
v2 2013-01-18

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SOP Objective

The objective of this SOP is to provide user instructions for the POINT app system provided by Mytrus, Inc.

Document Properties

Effective Date

Effective Start Date of This SOP
2012-12-20
Expiration Date of This SOP
2014-12-20

Approval

Role	Full Name	Title
Author	Sasha Zucker	Sr. Quality Manager
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Approver	Rob French	VP Product Development and Engineering

Applicability

- Site staff, principal investigators, and project team members for the POINT trial .
- Mytrus technology staff providing technical support to project team members for the POINT trial.

Referenced Documents

- Platelet-Oriented Inhibition in New Tia and minor ischemic stroke (POINT) Trial: Study Protocol Version 4.0, May 15, 2012
- [iPad User Guide: For iOS 6 Software](#)

Revision History

Version	Date	Remarks
1	2012-12-20	Initial publication for POINT Release 1.0.0.
2	2013-01-18	<ul style="list-style-type: none"> • Updated screen shots for app revisions. • Instructions for configuring Guided Access to restrict iPad usage to the POINT app. • Minor edits for clarity.

Statement of Authority

- Controlled documents can be distributed to assigned readers in both paper and electronic form.
- Authorized hard copies of originals should be stored at a secure central filing location.



- This document contains proprietary and confidential information.
- Access to and distribution of this document in printed or electronic form should be restricted to staff who are authorized to use the POINT system.

Responsibility for Ensuring Compliance

- Management is responsible for ensuring training and compliance with this document and monitoring its ongoing validity.
- Staff should follow the procedures detailed in this document and report any inability to do so to their respective managers.

POINT App User Guide

The following sections of this document provide instructions for using the POINT app system during the conduct of the POINT trial .

Introduction

This section provides introductory information for the POINT app system.

Who Should Read This User Guide

This user guide is intended for study staff (e.g., investigators and clinical research assistants) who will use the POINT app system during the conduct of the POINT trial .

POINT App System Overview

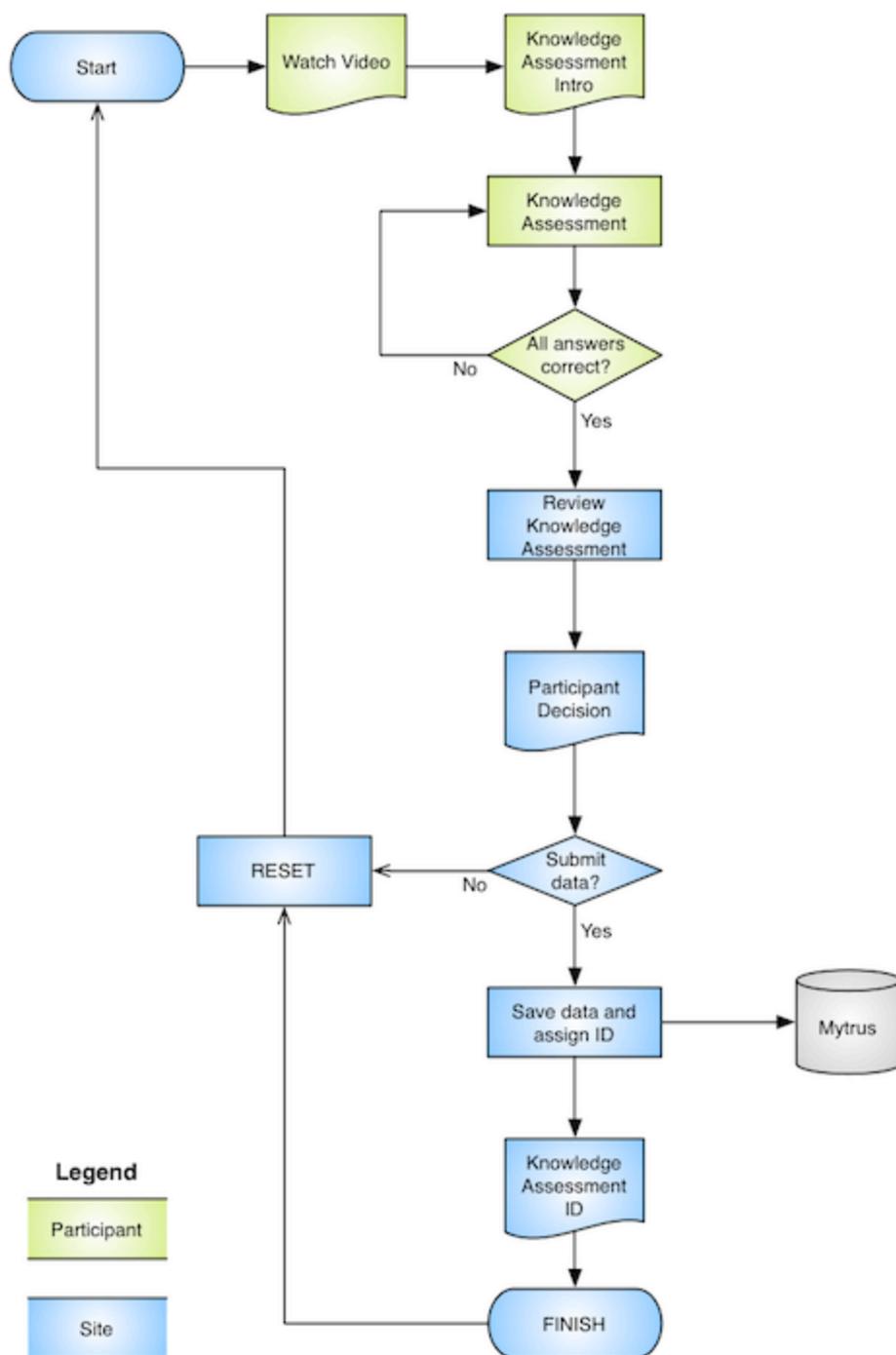
The POINT app is designed to be used as an aid in the consenting process. The six-minute video is a summary of the POINT study and is not meant to replace the discussions or the question-and-answer sessions that are required to consent patients into a research study. The POINT project team encourages all sites to use the POINT app as often as possible.

In addition to showing the patient the informational video, the app provides a knowledge assessment for the patient to demonstrate their understanding of the topics covered in the video. Additional metrics are captured during the patient's use of the app, such as the amount of time spent by the patient watching the video. Finally, study staff are able to capture the patient's decision about participation in the POINT trial. Study staff subsequently submit the data captured about the patient to a remote database. Project team members can review iPad app usage data in real-time on a secure web site.

The POINT app, the database, and the secure study website are referred to collectively in this User Guide as the *POINT app*.

Process Flow Diagram

The following diagram provides the standard process flow for use of the POINT app.



The process illustrated above is described as follows:

1. The site coordinator starts the app by tapping the POINT app on the iPad home screen and gives the iPad to the patient.
2. The patient watches the informational video. The patient may rewind, fast-forward, pause, and watch the video as many times as desired.
3. The patient reads the instructions for the knowledge assessment.
4. The patient completes the knowledge assessment, answering multiple-choice questions about the study. Each question has three answer options.
5. If the patient answers any questions in the knowledge assessment incorrectly, the patient is given additional opportunities to answer each missed question correctly. Additionally, the app provides the patient with a video

hint for each missed question. The knowledge assessment continues until the patient has selected the correct answer for each question.

6. The patient is instructed to return the iPad to the site coordinator, who reviews missed questions with the patient.
7. The site coordinator enters his or her initials and records the patient's decision about participation in the POINT study, indicating whether the patient signed the paper informed consent, wants more information, or does not want to participate in the study.
8. The site coordinator submits the patient's data.
9. The app displays a unique Knowledge Assessment ID for the patient for future reference by the site.
10. The site coordinator resets the app, preparing it for the next patient.



- Note that at step 8, the site coordinator can choose not to submit the patient's data, in which case the app will be reset for the next patient.
- In this case, data that has not been submitted from the app to the server will be lost.

Guidelines for Using the App

✓ The POINT app is intended to be used for the following purposes:

- To increase the enrollment rate at low-enrolling sites.
- To clearly summarize the main points of the trial.
- To enhance in the patient's understanding of the study.
- To help the patient feel involved in the study so that retention rates are improved.
- To standardize the information given to potential subjects across all sites
- To enhance protocol adherence, since more subjects are coming off study drug than initially anticipated.
- To enhance the consent process.
- To assist education of patients who are potential subjects for the POINT trial.

⊖ Use of the iPad and the POINT app should be limited as follows:

- The POINT app is **not** intended to replace the consenting process.
- The POINT app should **not** be used for all patients. For example, the POINT app should **not** be used with:
 - a patient who is incapable of holding the device due to stroke
 - a patient who is not familiar with using electronic devices, such as an iPad
 - a patient who does not wish to participate in the POINT trial
- The iPads provided for this study should **not** be used for personal, non-study-related purposes.

Getting Started with iPad

This system requires daily and frequent use of Apple's iPad platform. If you are not familiar with iPad, you should spend some time learning the basics of iPad before beginning the study.

You can download and read the [iPad User Guide](http://manuals.info.apple.com/en_US/ipad_user_guide.pdf) for free from Apple at the following web address:

http://manuals.info.apple.com/en_US/ipad_user_guide.pdf

System Requirements

This section specifies hardware and software requirements for the POINT app.

iPad Devices

The POINT app used in this system is specifically designed to run on the Apple iPad platform. The iPad hardware meeting the app's requirements will be provided to each investigative site by the study sponsor.

The POINT app is pre-installed on each iPad used in the study. The app cannot be removed from the iPad.

Internet Connection

The POINT app requires a high-speed wireless (WiFi) internet connection (e.g., Cable or DSL internet service). Please configure your iPad to connect to your site's WiFi network before attempting to use the POINT app.

 If you do not have a WiFi network at your investigative site, or if the WiFi network is temporarily unavailable, you will not be able to submit data to the server from the POINT app. In this case, you should contact your local IT help desk for assistance and should also notify the POINT project team concerning the issues with your local WiFi network (see [Getting Help](#)).

You can check the speed of your internet connection using a browser by going to the following web site:

<http://speedtest.net/>

Getting Help

If you require assistance while using the system, please contact:

Tess Bonham, CCRP
POINT Site Manager
tbonham@med.umich.edu

You may also contact Mytrus at the following e-mail address:

point-trial@mytrus.com

Setting Up the Study iPad

This section covers setting up each iPad before beginning conduct of the study at the investigative site.

 The tasks in this section need to be completed for each iPad at the investigative site.

The Site Representative

Each investigative site has one person who has been designated as the site representative. This person is primarily responsible for setting up the site's iPads and ensuring that they are stored securely. This person will also receive via e-mail the credentials that enable the POINT app to communicate securely with the remote study database.

 If you are not the site representative, you are not responsible for setting up the study iPad. Please continue to [Using the POINT App](#).

Connecting to Your Local WiFi Network

 For the POINT app to function correctly, your iPad **must** be connected to your site's local WiFi network.

Connecting the iPad to you local WiFi network is a topic that is beyond the scope of this document, as the steps to do so may differ significantly for each site. Please contact your site's IT support team for assistance with connecting the iPad to your site's local WiFi network.

For complete instructions on connecting an iPad to a WiFi network, refer the [iPad User Guide](#).

Charging the iPad Battery

To ensure that the conduct of the study is not interrupted, it is important to ensure that the iPad's battery is charged using the AC adapter and cable included with each iPad. Be sure to recharge each iPad as frequently as necessary during the course of the study (e.g., overnight or between visits with patients).

 If an iPad runs out of battery power during a visit, you can continue the patient's visit using one of the other iPads provided to your investigative site. However, any data captured on the original iPad will not be available on the replacement iPad.

For complete instructions on recharging an iPad's battery, refer the [iPad User Guide](#).

Setting the iPad Passcode

When powered on for the first time, each iPad will prompt you to set a passcode. The passcode is used to unlock the iPad when it has been locked manually or automatically. The use of the passcode also ensures that data on the iPad is encrypted and cannot be improperly accessed if it is lost or stolen.

The iPads used in this study are configured to auto-lock after 15-minutes of inactivity. The use of a passcode and auto-lock on each iPad is required for security and regulatory purposes and cannot be disabled.

After the passcode is selected, it can be shared with any member of the study staff at the investigative site, so that each member of the study staff can unlock and use the iPad during the conduct of the study.

At an investigative site, it is acceptable for the same passcode to be used for every iPad so that a member of the staff is not inadvertently locked out of an iPad during a patient's site visit.

 So that auto-lock of an iPad does not interrupt the conduct of the study, consider selecting a passcode that can be shared with and easily remembered by staff at the investigative site e.g., the site number. However, you should follow these security precautions:

- Do not choose a passcode that could be easily guessed, such as "Password" or "12345".
- Do not write or print the passcode on paper, which could allow the passcode to be obtained by an unauthorized party.

Authenticating the App with the Server

After the iPad's passcode has been set, it is necessary to enter the credentials for the app itself so that it can establish a secure, authenticated connection with the server running the database. The site representative should have received these credentials in an e-mail that was sent at study launch.

Setting Up the App Credentials

To set up the app credentials:

1. Unlock the iPad, if necessary, by entering the iPad passcode on the lock screen. The iPad home screen appears.
2. On the iPad home screen, locate the Settings app.



3. Tap the Settings app.
The Settings app launches.
4. In the menu on the left side of the screen, swipe up to locate the settings tab for the POINT app.
5. Tap the tab for the POINT app to view the settings for the app.



6. In the Account field, enter the e-mail address at which you received the credentials e-mail for the app.
7. In the Password field, enter the password that was provided in the credentials e-mail for the app.

NOTE

You must enter the account and password exactly as they appear in the e-mail, including lowercase and uppercase letters (your account and password are case-sensitive).

Confirming That the App Credentials are Correct

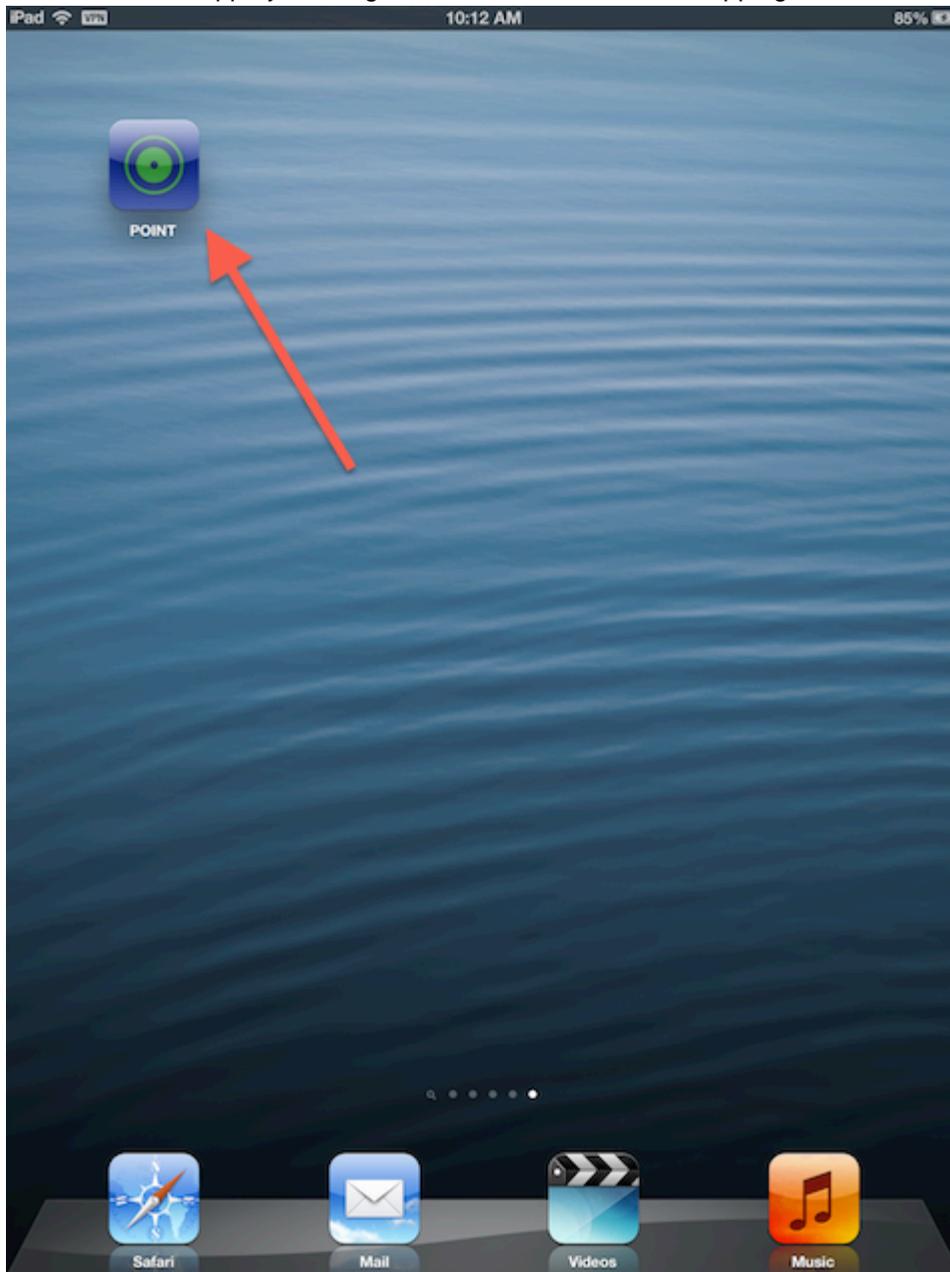
After you have entered the credentials, confirm that the app is able to authenticate with the server.

To confirm that the app credentials have been configured correctly:

1. Return to the iPad's home screen by pressing the iPad's home button (on the front of the iPad below the

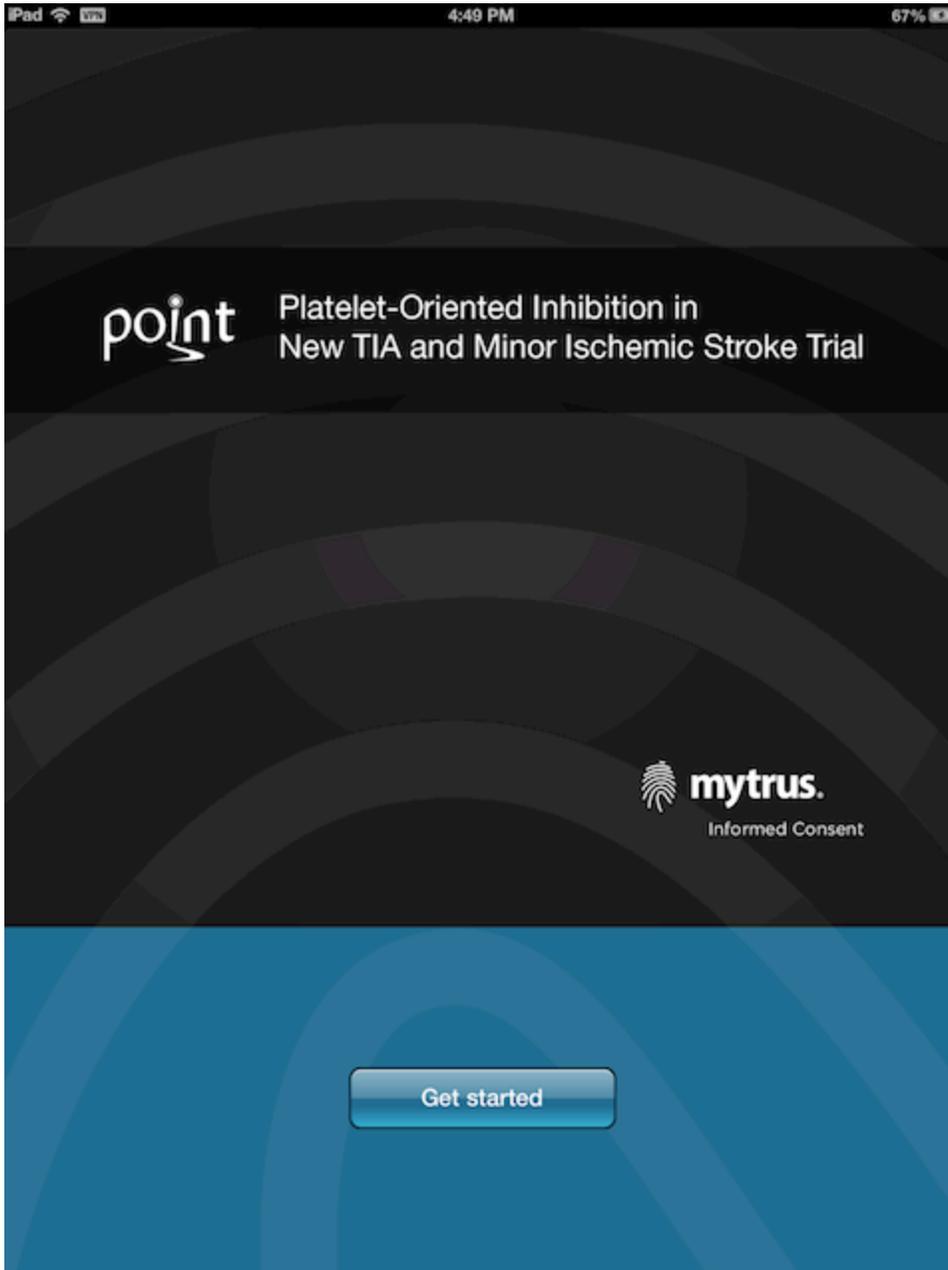
screen).

2. Start the POINT app by locating it on the home screen and tapping it.



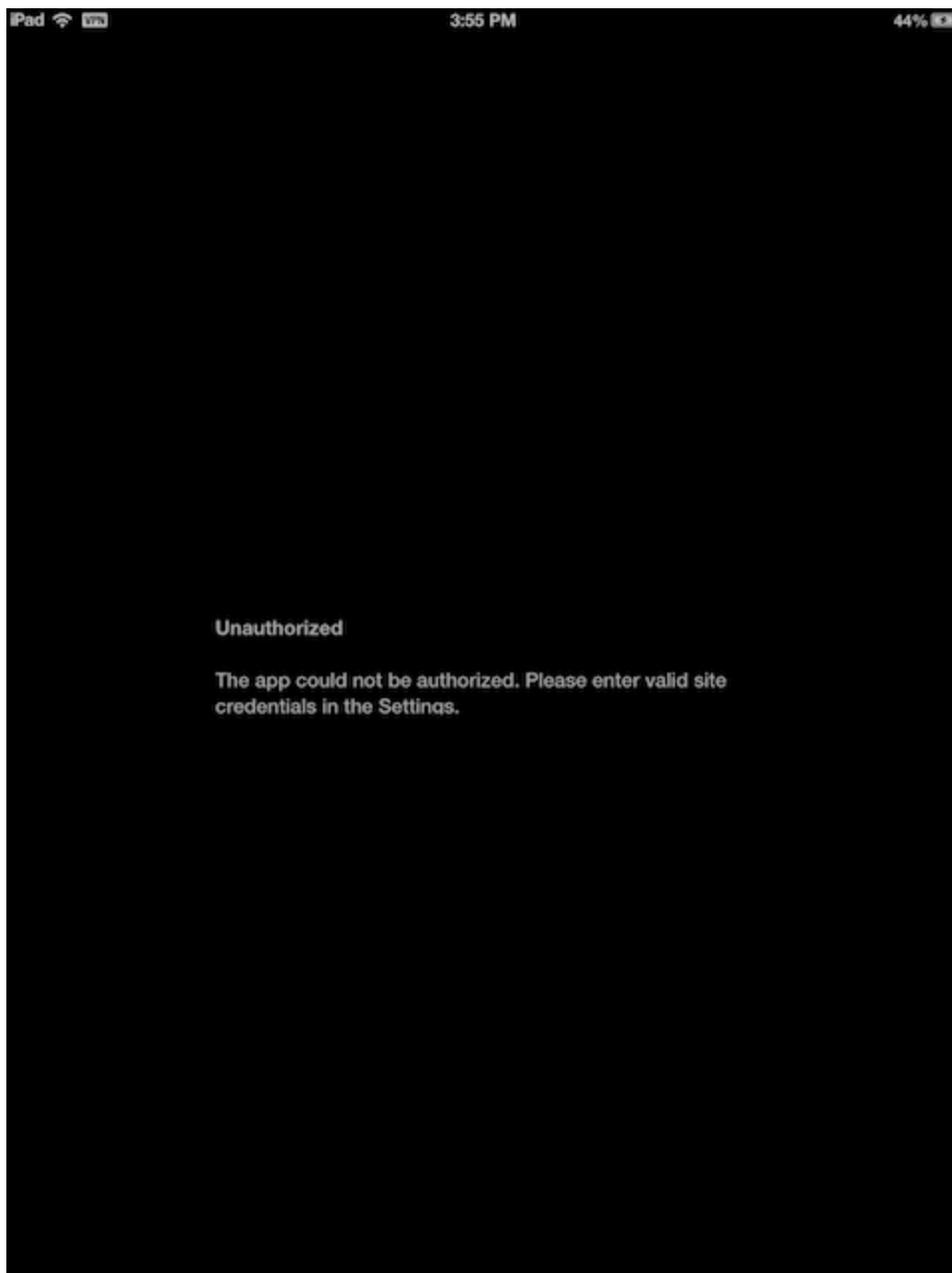
- ✓ If you do not see the POINT app, swipe your finger tip across the iPad display from right-to-left to view the other available home screens.

If the site's credentials were entered correctly, the app's first screen appears.



Troubleshooting App Authentication

If the app cannot authenticate successfully with the server, you will see the following screen when the app launches:



If you see this screen, check that you entered the site's credentials correctly in the Settings app, as discussed in [Setting Up the App Credentials](#).

If you are still unable to get the app to authenticate with the server, take the following steps:

- Ensure that your iPad is connected to your site's WiFi network correctly.
- Contact your site's IT support team (helpdesk) to ensure that the local network is functioning correctly.
- Contact the POINT project team for assistance (see [Getting Help](#)).

Restricting Use of the iPad with Guided Access

To ensure that the iPad can only be used for the POINT study, you can enable the iPad's Guided Access feature. When the Guided Access feature is active, a user cannot switch from the POINT app to other apps on the iPad.

For complete instructions on the Guided Access feature, refer the [iPad User Guide](#).

Configuring Guided Access

To configure Guided Access:

1. Unlock the iPad, if necessary, by entering the iPad passcode on the lock screen.
The iPad home screen appears.
2. On the iPad home screen, locate the Settings app.
3. Tap the Settings app.
The Settings app launches.
4. In the menu on the left side of the screen, swipe up to locate the General settings tab.
5. In the menu on the right side of the screen, swipe up to locate the Accessibility menu option.



6. Tap the Accessibility menu option.
Tap Guided Access.



7. Tap the switch to the right of the Guided Access menu item to turn on Guided Access.



8. Tap Set Passcode.



9. Enter and confirm a passcode for Guided Access.

 See [Setting the iPad Passcode](#) for guidelines on selecting and using passcodes on the iPad.



When you have successfully confirmed your passcode, the iPad is ready to use Guided Access.

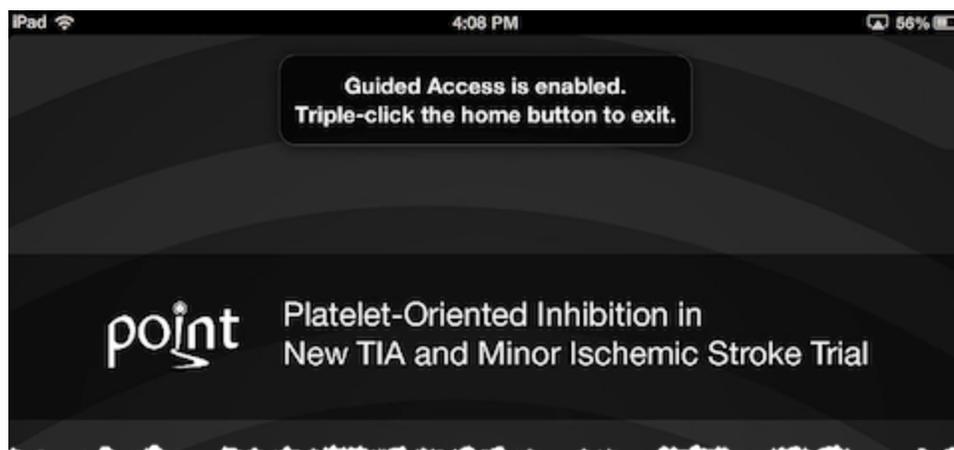
Starting Guided Access in the POINT app

To restrict the iPad so that only the POINT app can be used:

1. Start the POINT app by locating and tapping the app on the iPad home screen ([Confirm That the App Credentials are Correct](#)).
2. Triple-tap the iPad's home button (tap the iPad's home button three times in rapid succession). The Guided Access menu appears.
3. Start Guided Access by tapping Start at the top-right of the screen.



The iPad will now be in Guided Access mode and will remain in the POINT app. The iPad cannot be switched to another app while Guided Access mode is enabled.

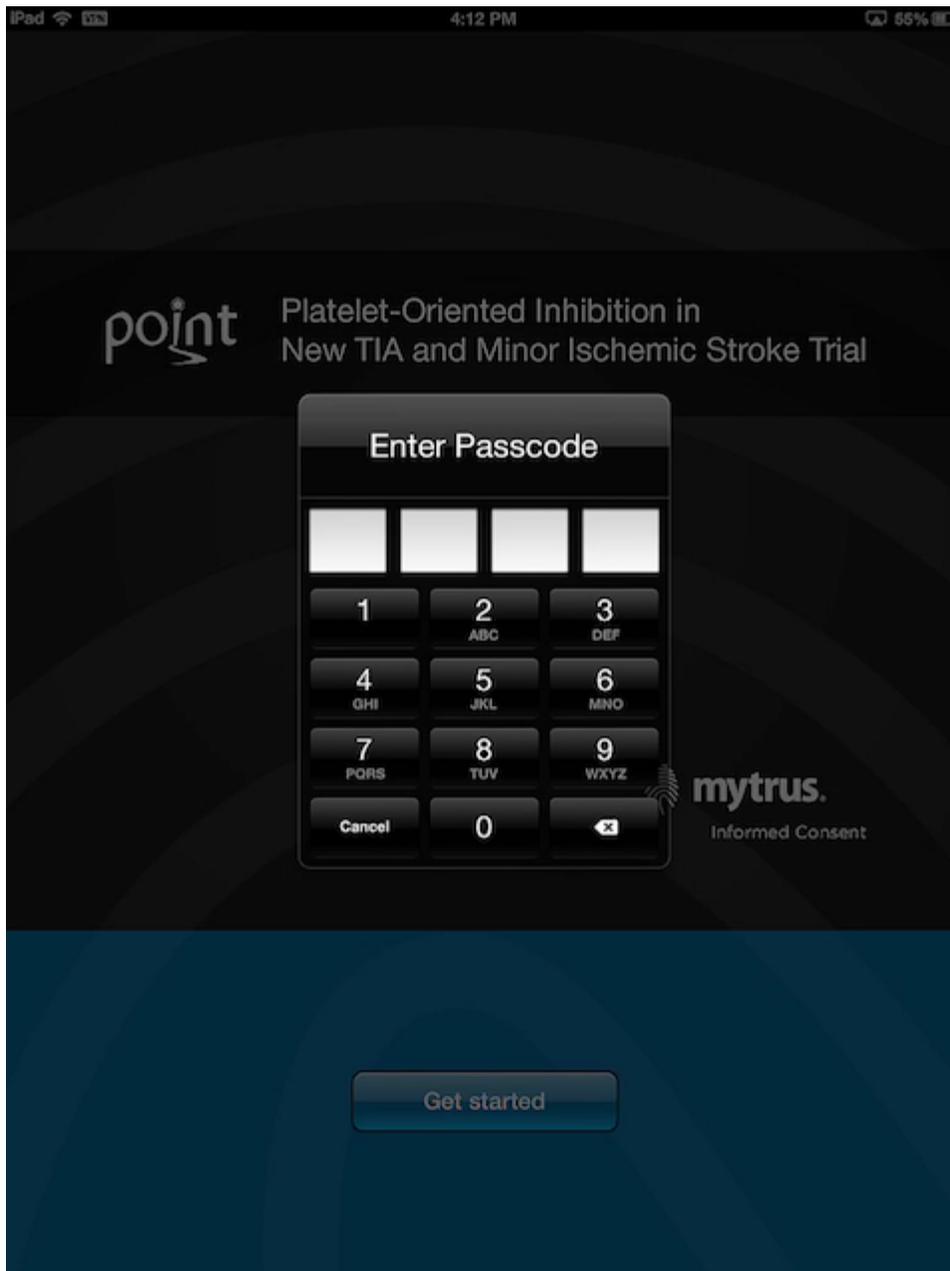


 The iPad's hardware volume controls will not work while Guided Access mode is enabled. For the video portion of the app, the volume can be set using on-screen controls (see [Playing the Video](#)).

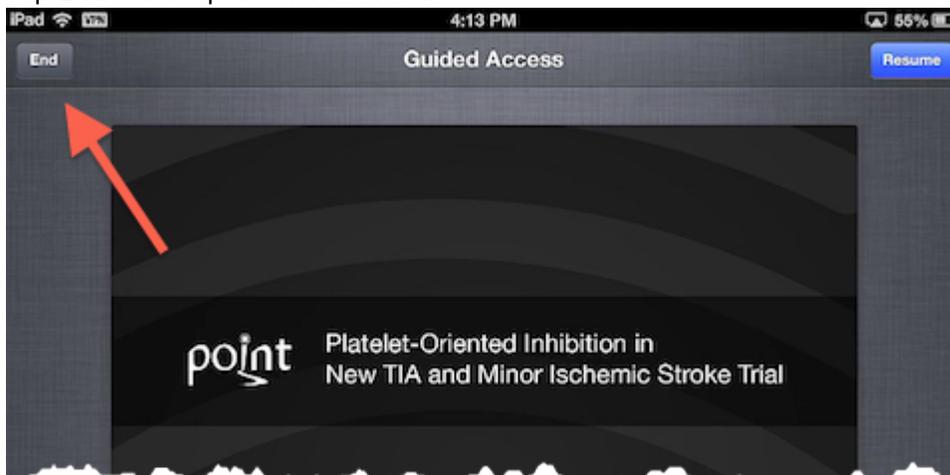
Ending Guided Access

To end Guided Access so that other apps can be used with the iPad:

1. Triple-tap the iPad's home button.
2. Enter the passcode that was selected for Guided Access in the iPad's Settings.



3. Tap End at the top-left of the screen.



The iPad ends Guided Access mode.

Using the POINT App

This section provides instructions for using the POINT app.

Starting the App

To start the POINT app, locate and tap the app's icon on the iPad home screen as discussed in [Confirm That the App Credentials are Correct](#).

Tap Get Started to continue to the Informed Consent Video screen of the app.



Language Selection

- For Release 1.0.0 of the POINT app, English is the only language available.
- Future releases of the POINT app will enable selection of other languages.

Navigating the App

After you tap Get Started, the Video screen of the app appears.

The tabs at the bottom of each screen of the app allow you to go to other sections of the app out of the intended order, if necessary.

The highlighted tab indicates that section of the app that you are currently viewing.



Section	Purpose
Video	<ul style="list-style-type: none"> • Watch the POINT informational video.
Learn	<ul style="list-style-type: none"> • Take the knowledge assessment. • Review the patient's answers to the knowledge assessment.
Participate	<ul style="list-style-type: none"> • Record the patient's participation decision. • Save the patient's data to the remote database. • Reset the app without saving any data.

Playing the Video

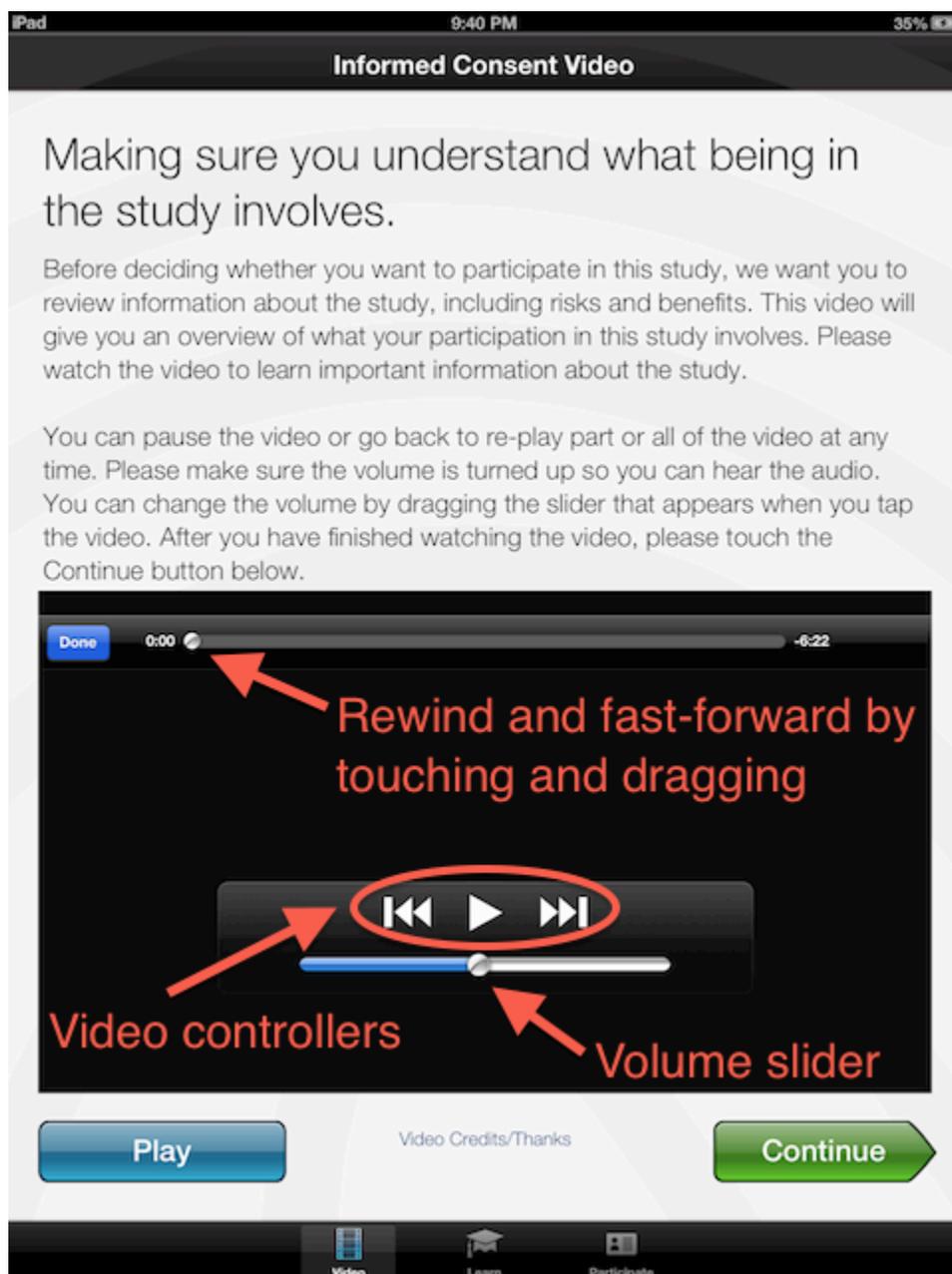
On the Video screen of the app, you can play the app by tapping the Play button. Once the video starts playing, the Play button changes to a Pause button, allowing you to easily pause the video.

Using the Video Controls

The video controls that are displayed on the bottom half of the video panel allow you to pause, play, rewind, and fast-forward the video and to change the volume of the video.

You can also rewind and fast-forward the video using the controls that appear on the bottom half of the video or by touching and dragging the "scrubber" control that appears at the top of the video panel

The video controls will disappear after a few seconds while the video is playing. You can cause the video controls to reappear by tapping the video panel on the screen.



Adjusting the Volume

You can adjust the volume of the video's sound track by touching and dragging the "slider" control that appears below the play button.

 When Guided Access is enabled, the volume buttons on the side of the iPad do not function. In this case, you can only use the slider control to adjust the volume of the video.

Viewing the Video in Full Screen

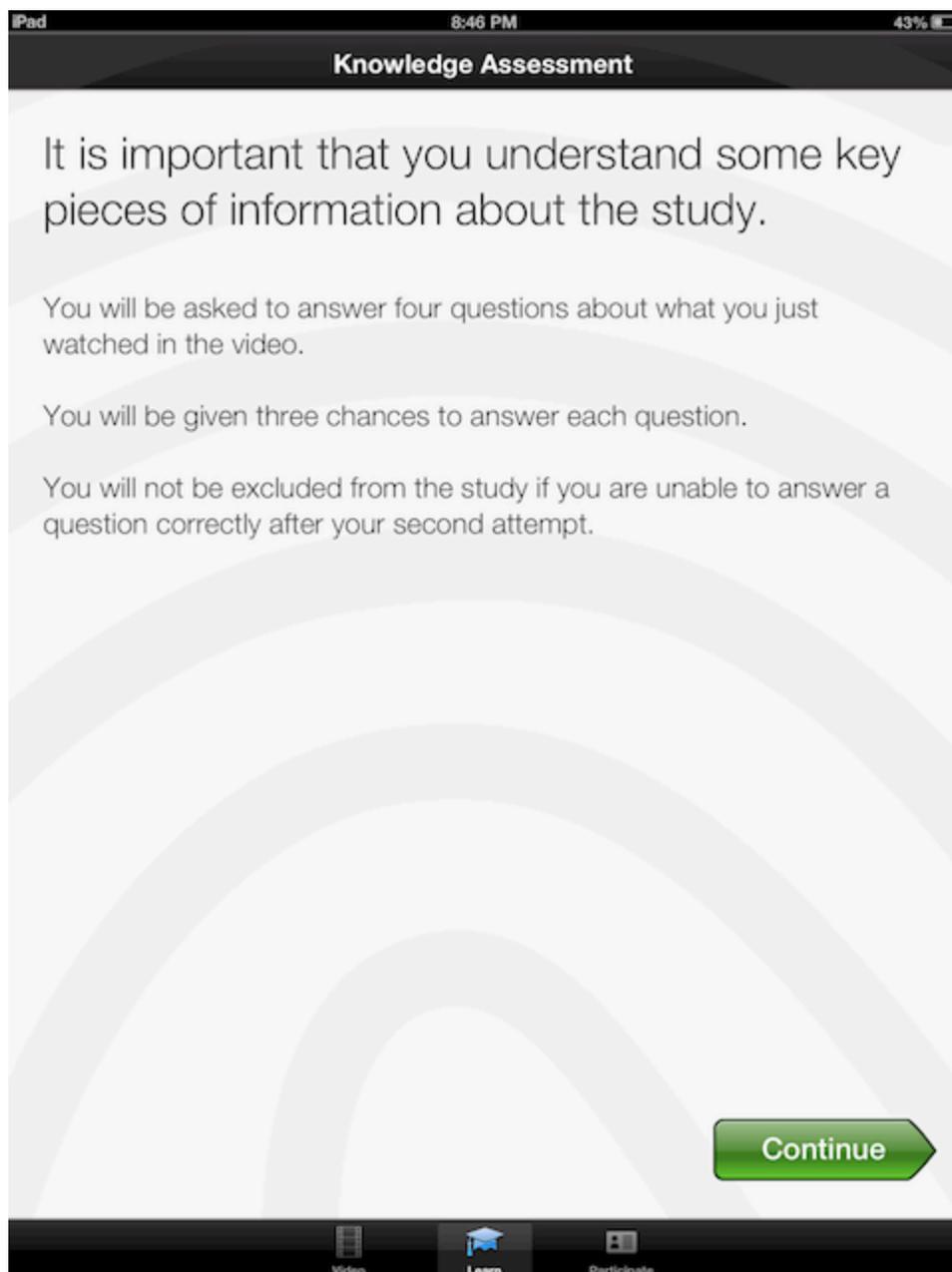
The video can be viewed in full-screen mode by rotating the iPad to a horizontal ("landscape") position. The video automatically resizes to fill the entire iPad screen during playback.

When the video has finished, you can continue to the knowledge assessment by tapping Continue.

At any time while using the app, you can return to the Video screen to watch the video again by tapping the Video tab.

Completing the Knowledge Assessment

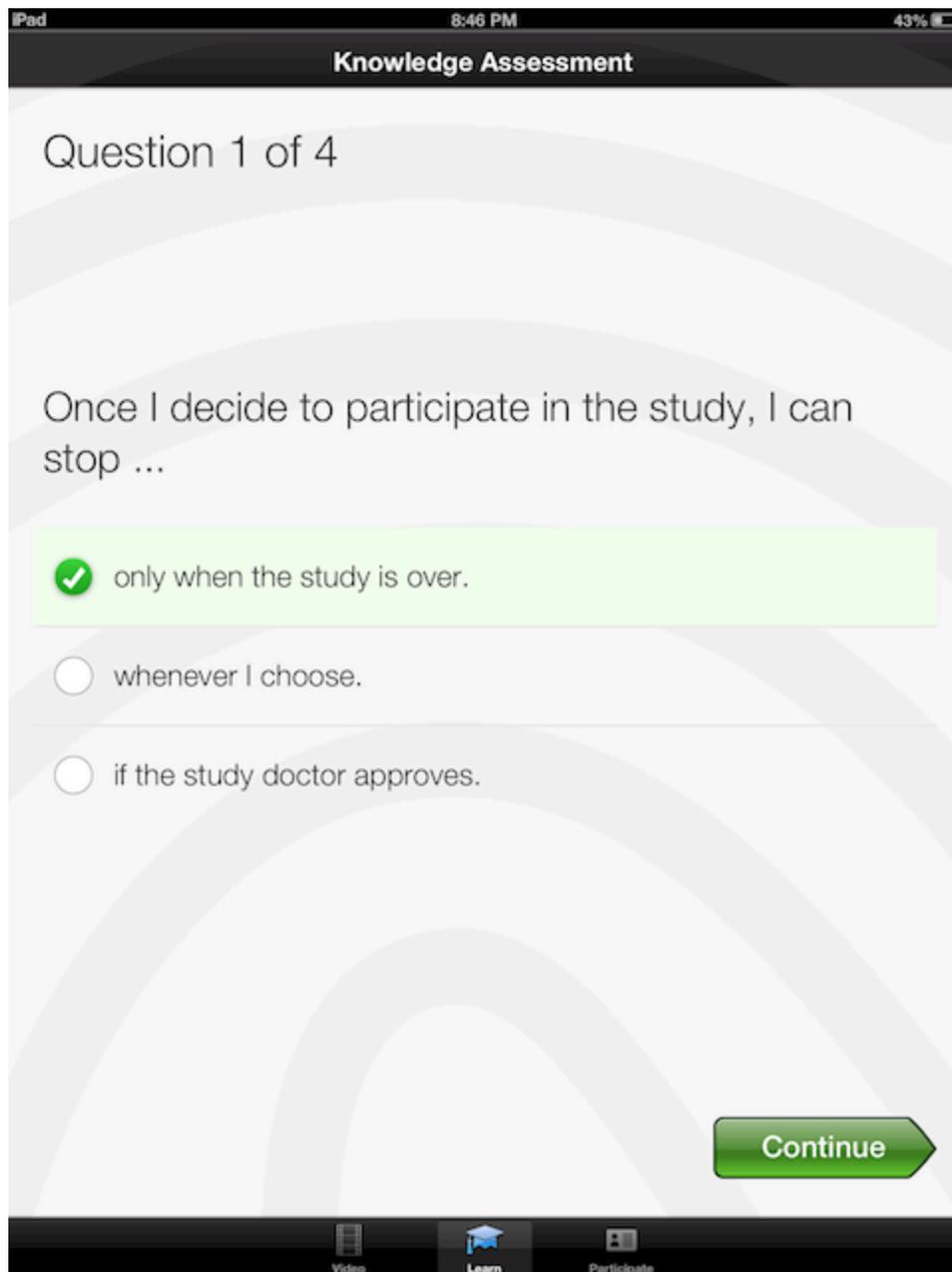
When you tap Continue on the Video screen, the app displays the instructions for the knowledge assessment:



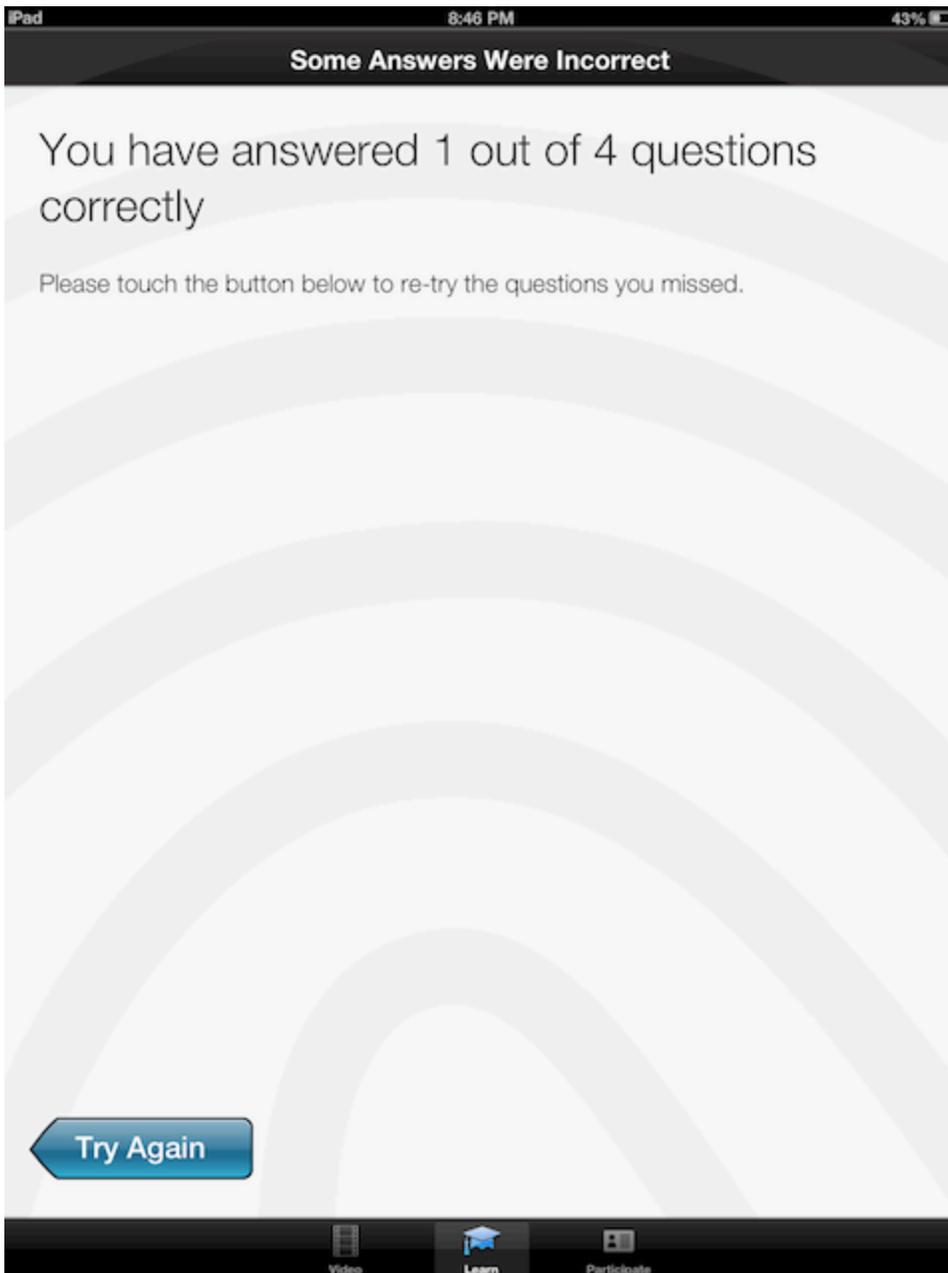
When you tap Continue, you will be prompted to answer four questions.

Each question in the knowledge assessment has three answer options, only one of which is correct.

To select an answer option, tap the answer and then tap Continue:



If any of the questions were answered incorrectly, you will have the opportunity to answer each missed question correctly. It is not possible to fail the knowledge assessment.

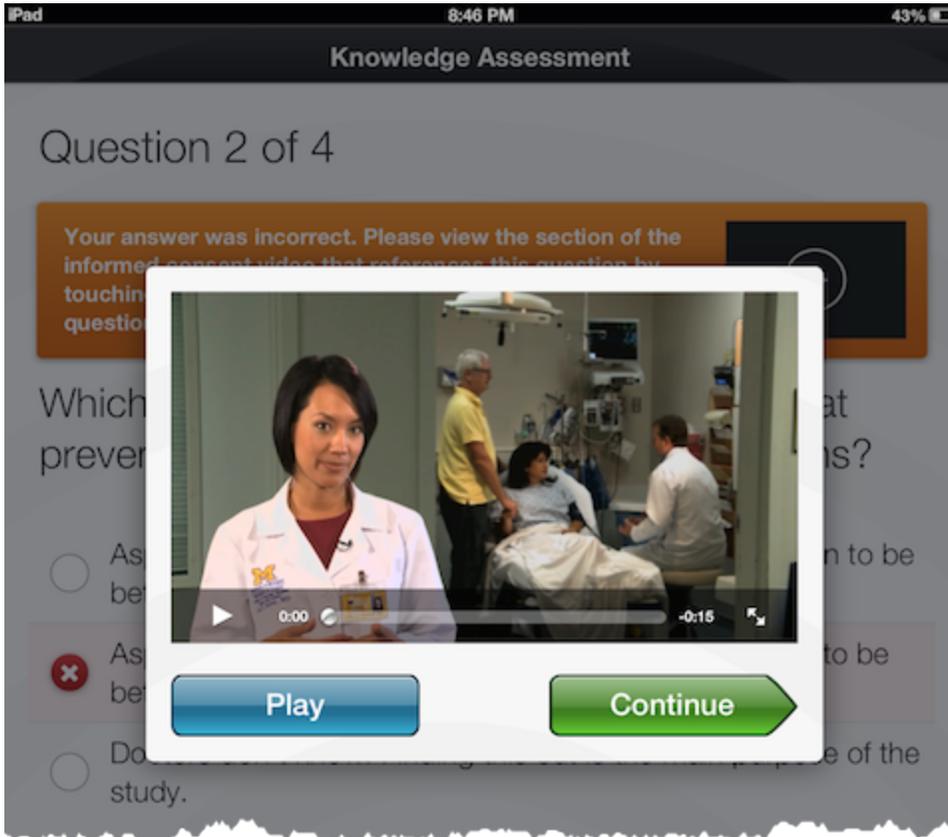


Tap Try Again to view the incorrectly answered questions and attempt to select the correct answer.

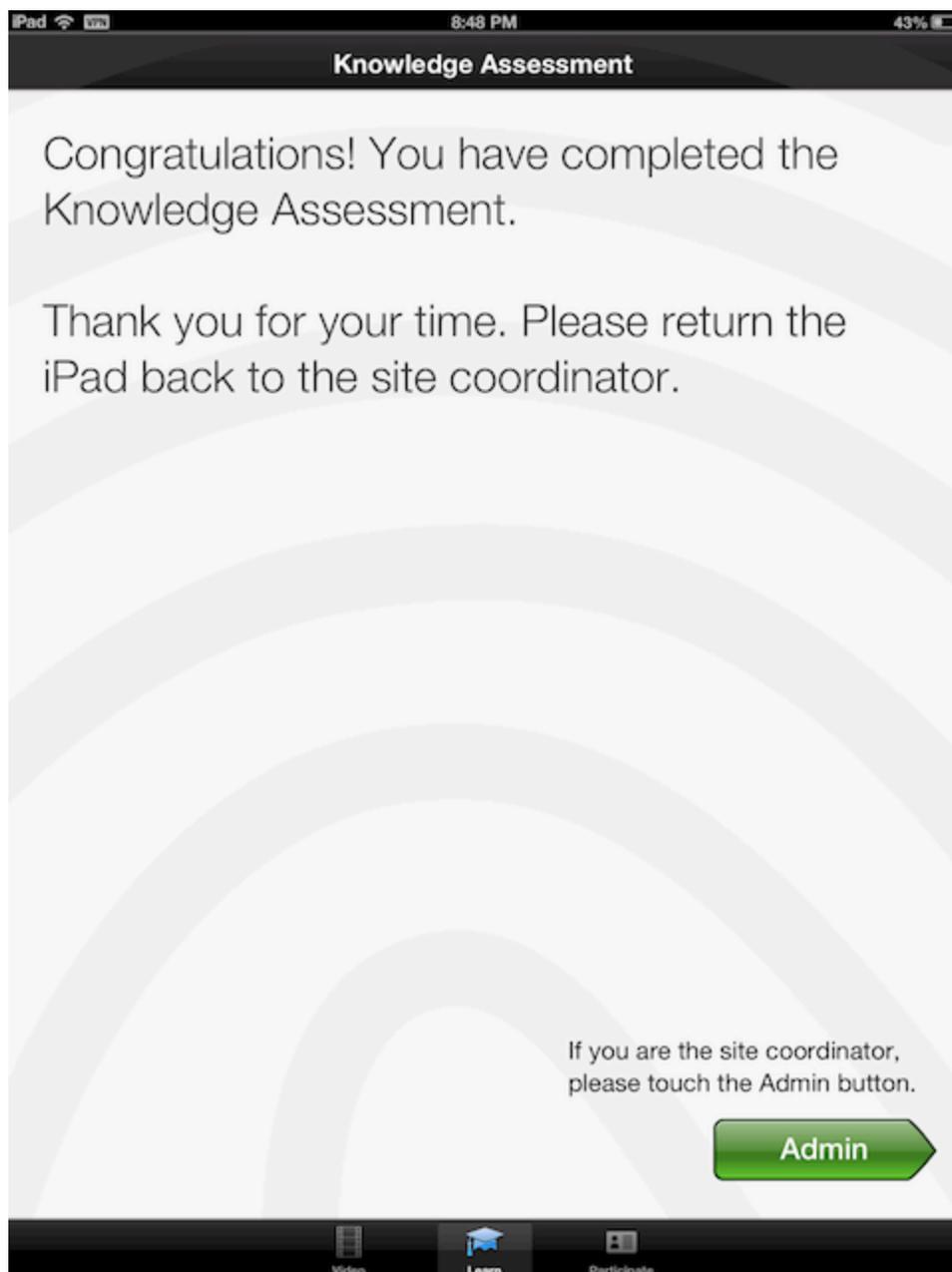
When viewing a missed question, your previous answer will be marked as incorrect and cannot be selected again.



By tapping the video icon at the top-right of the screen, you can view a video hint to help you determine the correct answer.



After you have answered all of the questions correctly, the app displays the following screen:



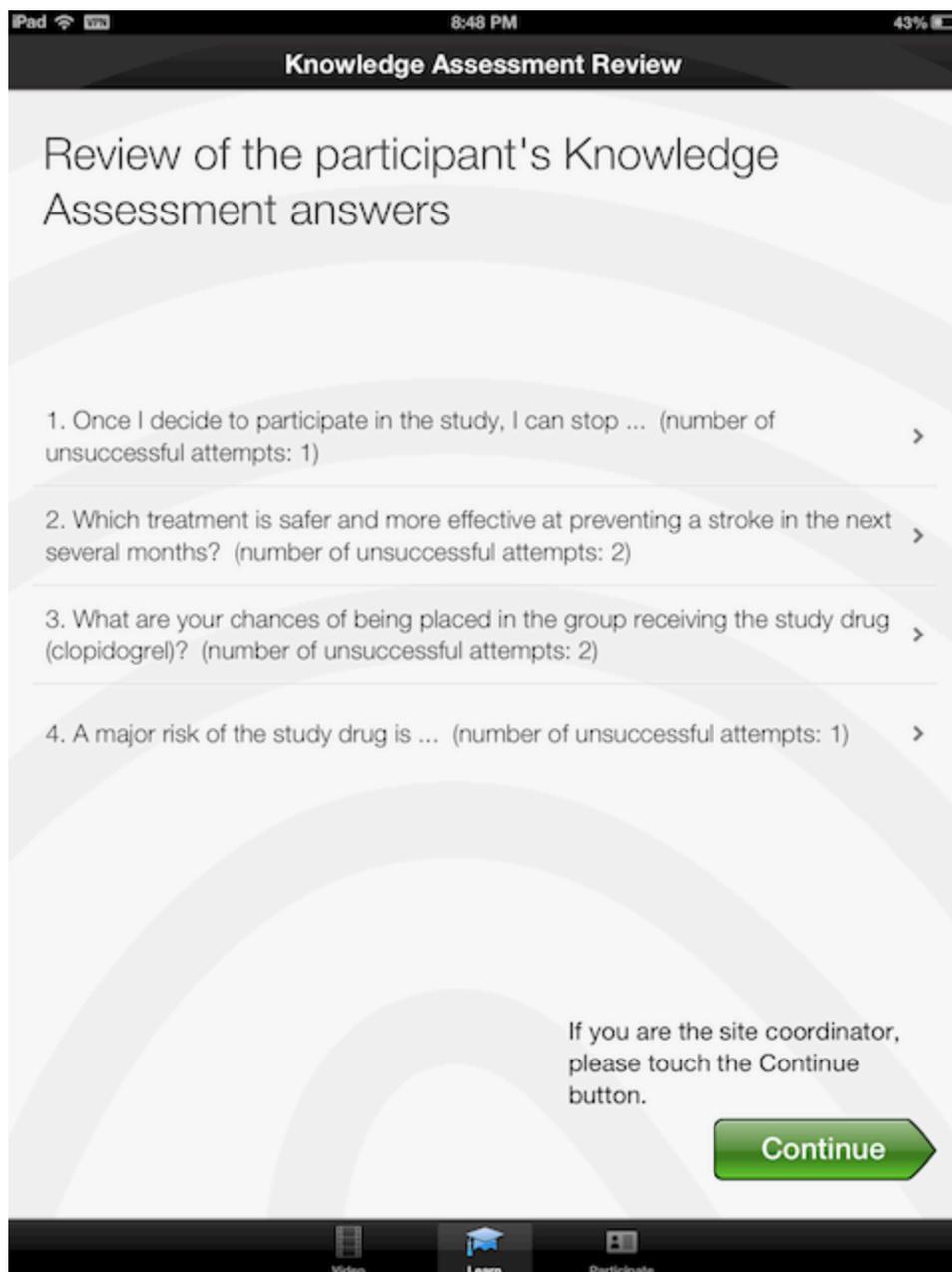
-  If you leave the knowledge assessment before it has been completed, tapping the Learn tab will return you to the last unanswered or incorrectly answered question.

Reviewing the Patient's Answers

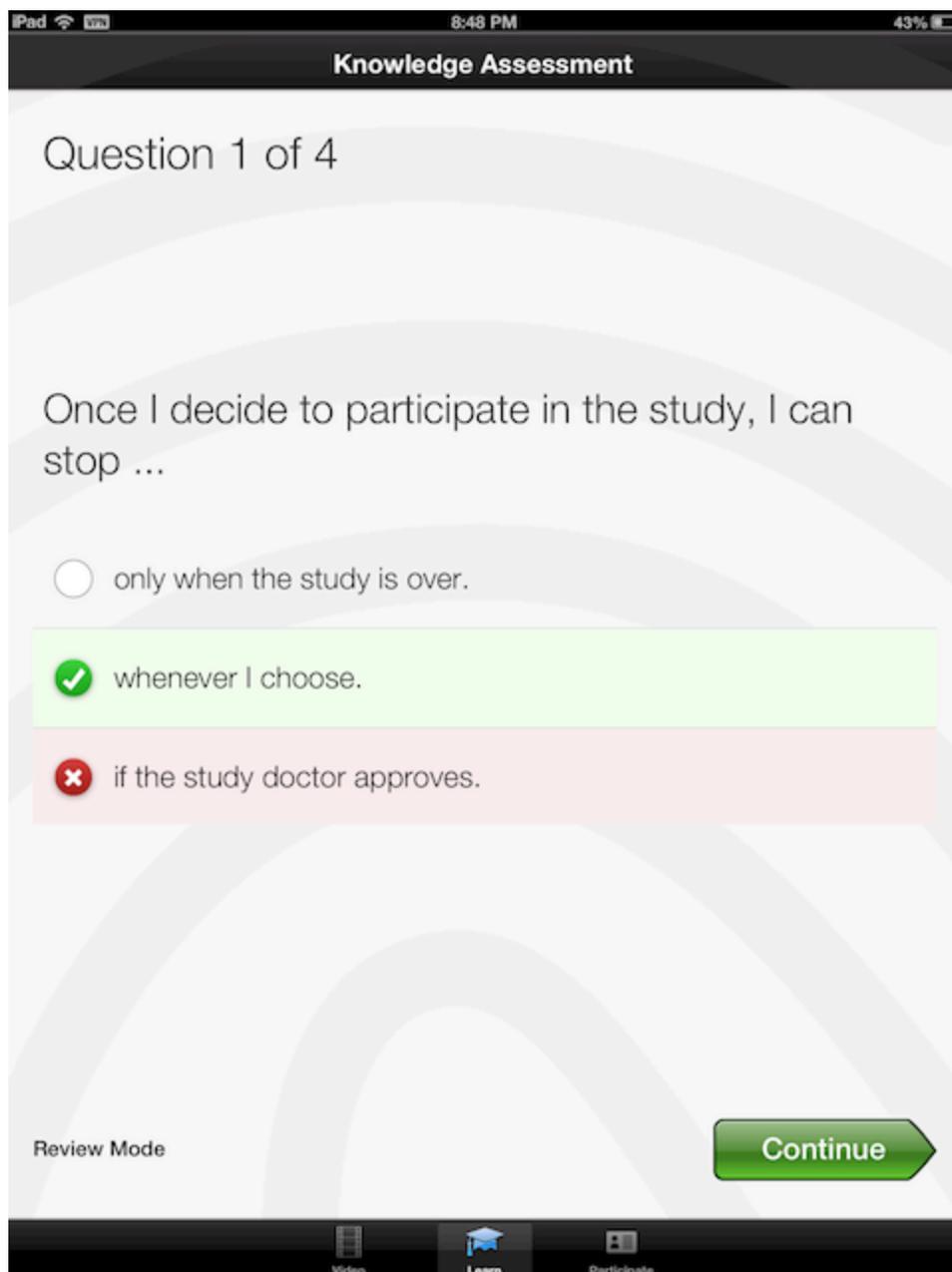
Once the knowledge assessment has been completed, you can review the answers by tapping Admin at the bottom-right of the screen.

The questions are displayed with the number of unsuccessful answers for each.

-  After the knowledge assessment has been completed, you can return to the Knowledge Assessment Review screen by tapping the Learn tab.



You can view a question again by tapping the question. Any incorrect answers that were selected are marked with a red "X".



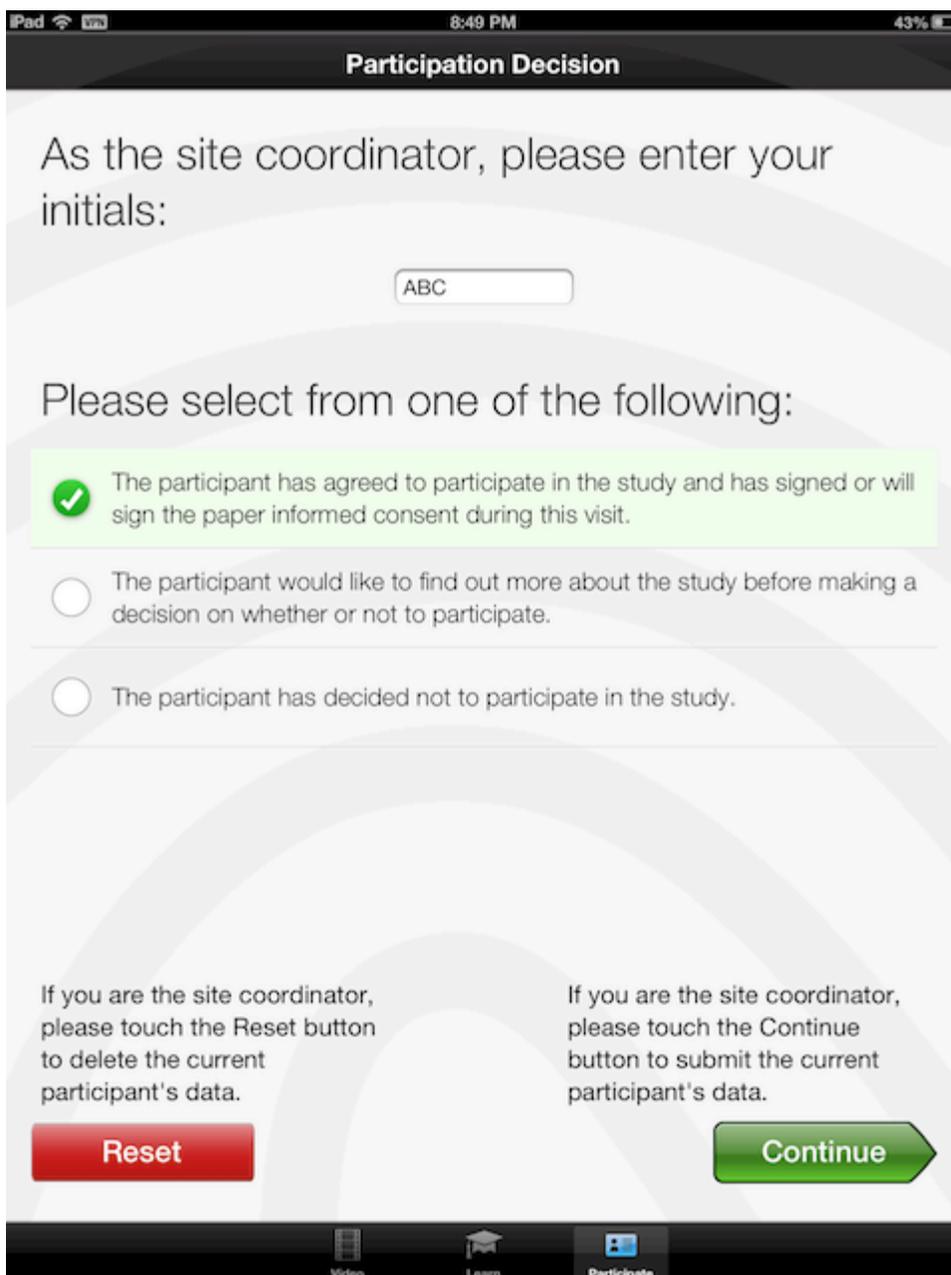
Recording the Participation Decision

When you have finished reviewing the knowledge assessment results, you can continue to the Participate section of the app by tapping Continue.

The app displays the Participation Decision screen.

Complete the Participation Decision screen as follows:

1. Enter your initials. You may use two or three letters.
2. Select the patient's participation decision.

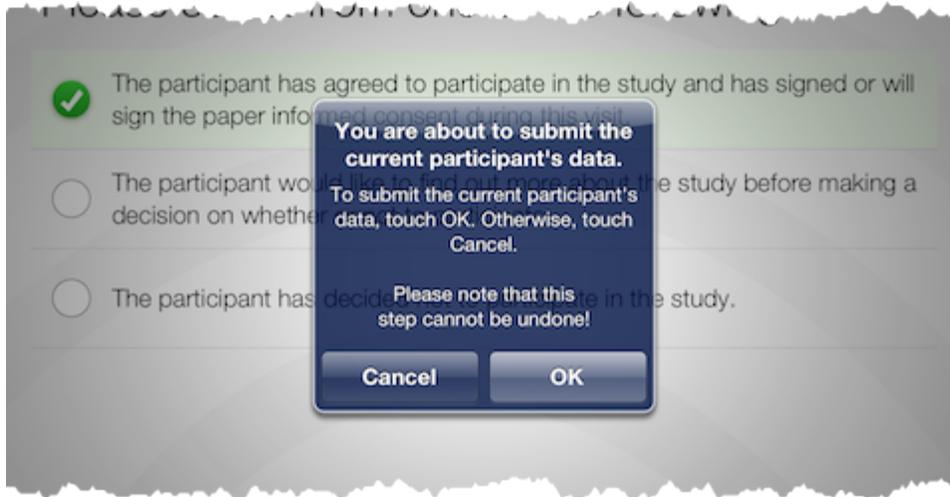


3. Tap Continue.

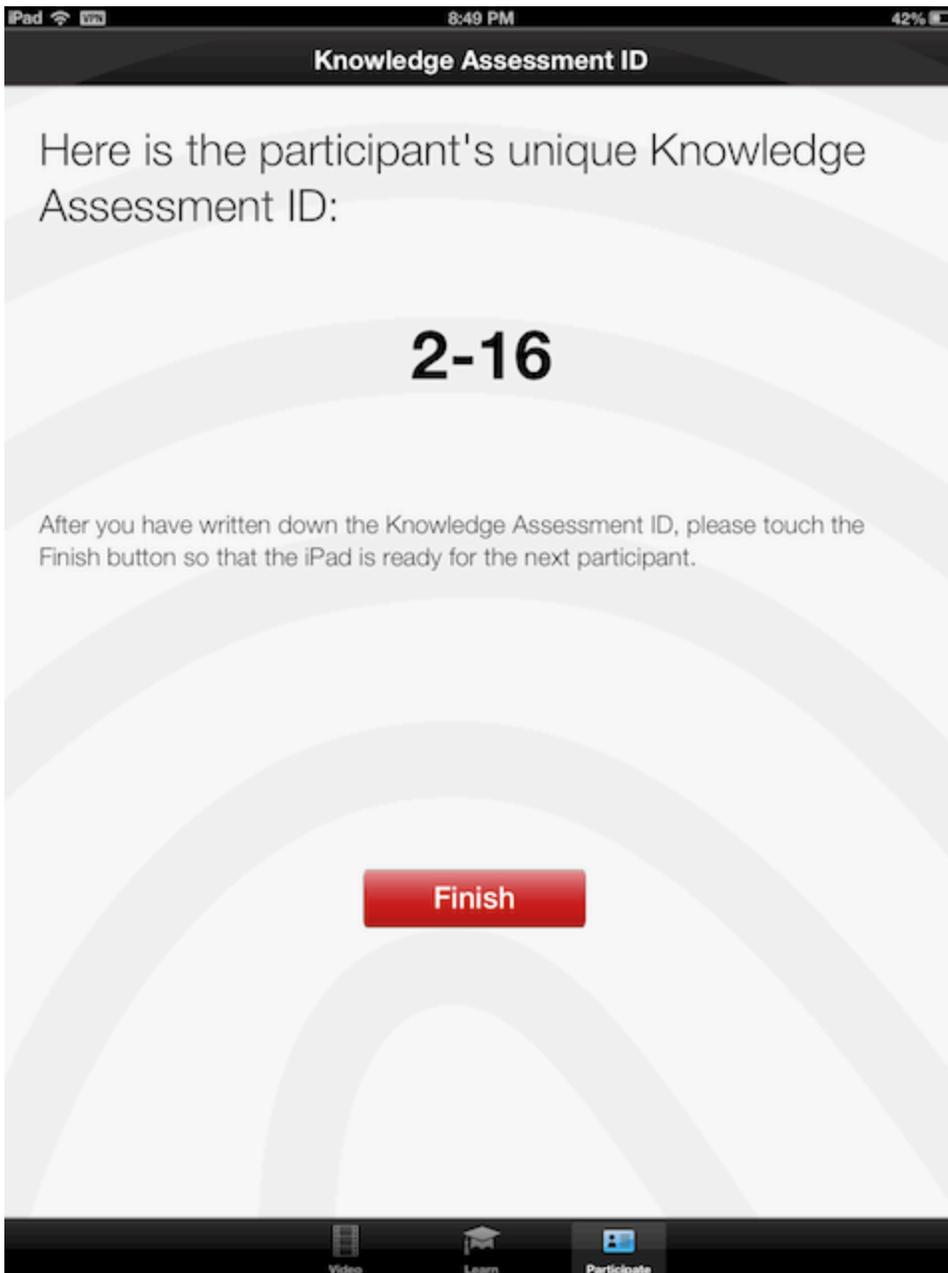
The app displays an alert prompting you to confirm submitting the patient's data.

⚠ Internet Connection Required

- To submit the patient's data to the Mytrus server, the iPad must be connected to the Internet via your site's WiFi network.
- If you do not have access to the Internet from your location at the site (e.g., because the WiFi network is not in range), please go to a location at your site where the WiFi network is available before attempting to submit the patient's data to the Mytrus server.



4. To confirm submitting the patient's data, tap OK.
The app displays the Knowledge Assessment ID for the patient. You should note this ID for future reference.



Problems Submitting Data

If the app is unable to connect to the Mytrus server, you will see an alert indicating that a network error has occurred.

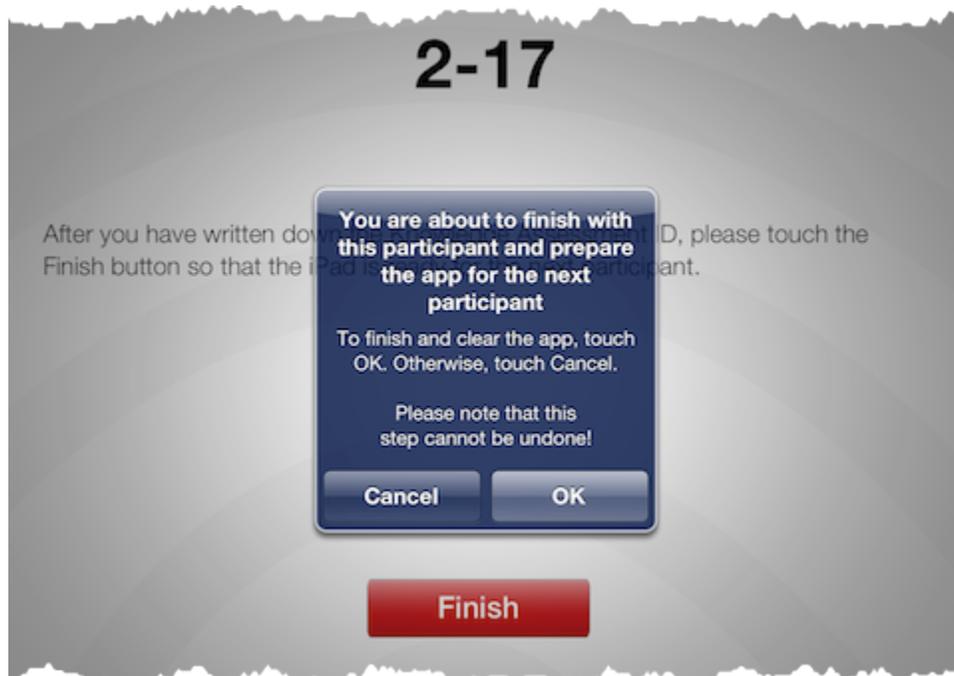


You can attempt to submit the data again by tapping Try Again. However, if you continue to encounter a network error when submitting data, you should contact the POINT project team for assistance (see [Getting Help](#)).

Resetting the App After Submitting the Patient's Data

After you have submitted the patient's data, you should reset the app so that it is ready for the next patient. To do so, tap Finish.

The app displays an alert prompting you to confirm resetting the app.

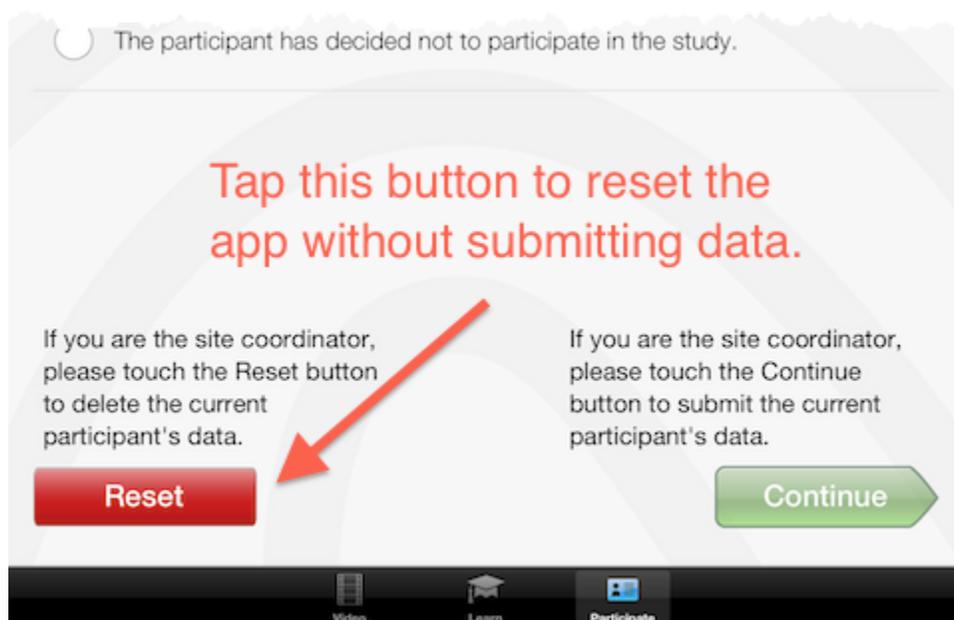


To confirm resetting the app, tap OK.

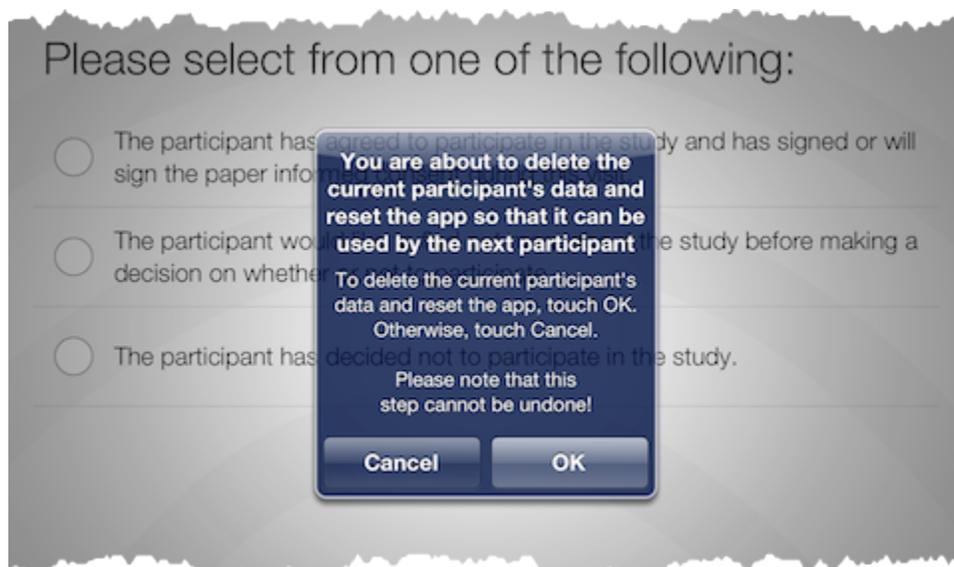
The app displays the first screen again and is ready to be used with the next patient.

Resetting the App *Without* Submitting Data

If you need to reset the app without submitting data to the server (for example, if you started using the app in error), you can do so by tapping Reset on the Participate screen.



When you tap Reset, the app displays an alert prompting you to confirm resetting the app.



To confirm resetting the app, tap OK.

The app displays the first screen again and is ready to be used for the next patient.