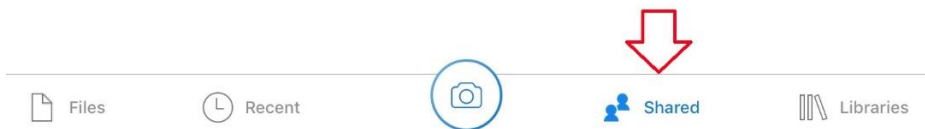


## **Section A: Informed Consent (only in Patient Pre-Coaching)**

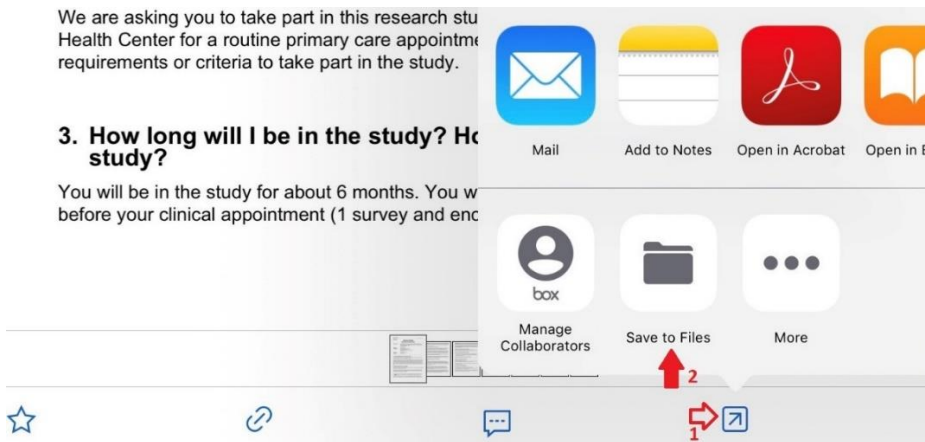
- **Step 1:** Click to Open the OneDrive app on the iPad



- **Step 2:** Click on the Shared folder on the bottom of the screen



- **Step 3:** Select the folder labeled “Patient Consents – RCT Prostate Cancer”
- **Step 4:** Select the appropriate Consent documents
  - **BASELINE Patient consent\_and\_AV\_consent.pdf**
    - Completed for Baseline group patients only
    - Includes both informed consent and audio visual consent forms
  - **Patient consent\_AV\_consent.pdf**
    - Completed for all greater study patient groups (control and intervention)
    - Includes both informed consent and audio visual consent forms
- **Step 5:** Save a copy of the document on the iPad
  1. Click the export tab at the top right of the document
  2. Click on “More Apps”
  3. Then select “Save to Files”
  4. Final step, Select “Acrobat” and “Add”
    - Replace existing item if previous version still saved on iPad



- **Step 4:** Open the document in Adobe Acrobat
  1. Click the Home button on the iPad to return to the home screen
  2. Select and open the “Acrobat” app



3. Click on the ellipsis (...) next to the consent file name and then select “Rename” to add study id number at end of the file name
    - Study ID = Participant Number, Initials, \_Date
      - i.e. “01JT\_070819”
  4. After renaming the file, open the document by selecting it
- **Step 5:** Review consent form with the participant and **RECORD PARTICIPANT SIGNATURE/Initials** using the Adobe signature tool in appropriate sections of consent form:

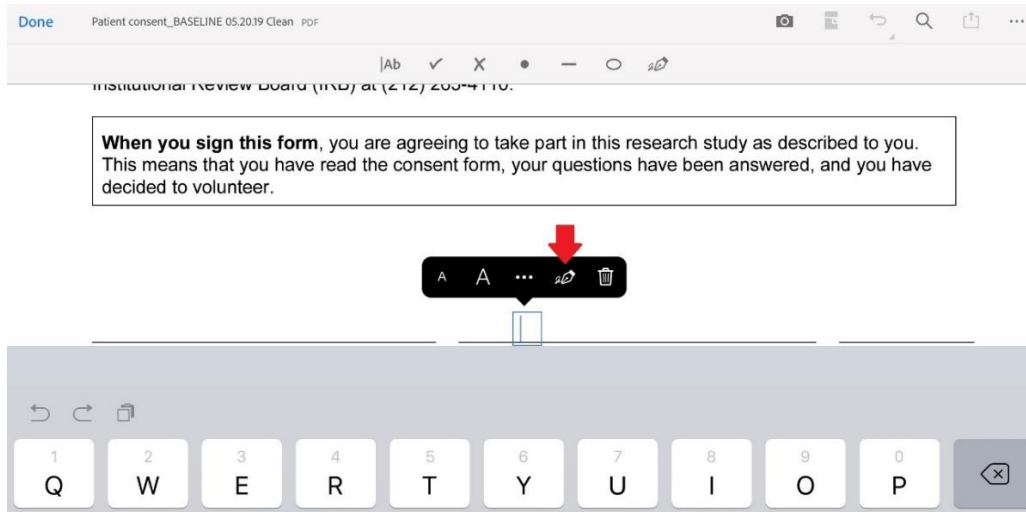
When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

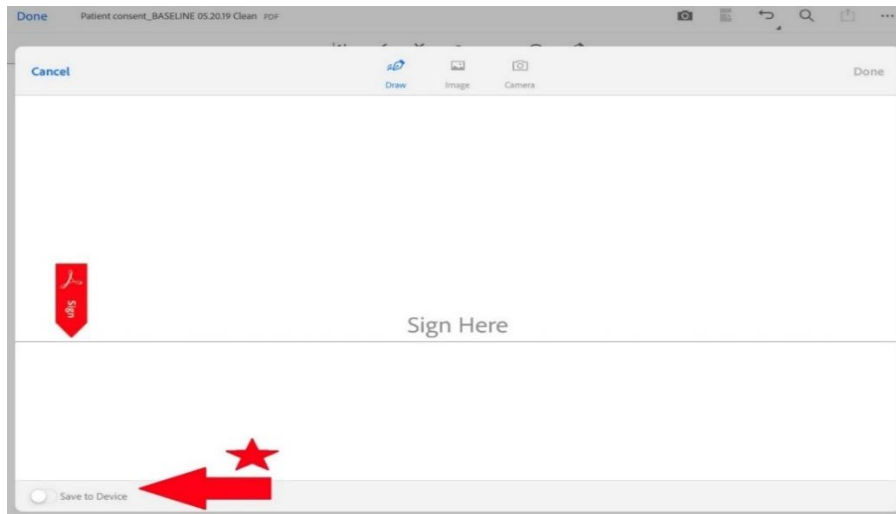


- Once you click the Adobe sign tool, **click on “Fill & Sign”**
  - Click on the area you would like to add text or a signature

- Text can be entered by typing with the keyboard that will pop up
- For Signatures, click on the pen tool to open the signature box:



- **\*\*\*In the signature box, Uncheck "Save to Device"\*\*\*** before clicking Done to add signature



- If signature was saved to device, next time you click the signature pen the previously entered signature will automatically appear
- To delete the signature click on the pen tool on the top right of the navigation bar and the “-” symbol next to the signature

Done

Patient consent\_05.20.19 Clean\_BASELINEtt PDF

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Study #: S16-00514  
Version date: 05/20/2019

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**16. The Institutional Review Board (IRB)**

The IRB reviews all human research studies – including rules and guidelines designed to protect the rights and studies. The IRB also reviews research to make sure that The NYU IRB Office number is (212) 263-4110. The NYU

- Doctors, nurses, non-scientists, and people from the community

test

Create Initials

government  
research  
possible.  
up of:

**17. Who can I call with questions, or if I'm concerned about my rights as a research subject?**

- After you finish entering text/ signature, click on “Done” in the upper left corner to exit the “Fill & Sign” mode
- The following areas on the consent documents need signatures/initials:
  - Patient Consent Forms
    - Section 15: Optional permission for future (check box & patient initials)
    - Section 17: Consent agreement
      - Printed Name and Signature of Subject (patient), Date
      - Printed Name and Signature of Person Obtaining Consent (CHW), Date
  - Audio Visual
    - Name and Signature of subject (patient), date
    - Name and Signature of Person Obtaining Consent (CHW), date
- **Step 6:** Securely email the signed consent form to the Research Data Associate (RDA) AND yourself:
  - Clicking the send tool in the top right of the document, then click “share a copy”, and “Mail”
    - In the subject field, make sure to type in [SAFE] at the end of the subject line to secure the email after study id number
      - For example, “Subject: 01JT\_070819 [SAFE]”
    - RDA: Jerry Thomas, [jerry.thomas@nyulangone.org](mailto:jerry.thomas@nyulangone.org)
      - Office: (646) 501-9836
- **Step 7:** Contact RDA to tell you whether patient is randomized to Intervention or Control group
- **Step 8:** Upload the consent document to REDCap (“Step 2 in Section D Uploading Consent Form)
- **Step 9:** Print a copy of the signed consent form at the clinic and give it to the patient before they leave the appointment
  - Access available computer and printer in clinic during appointment to print consent form from your email to give to patient

## Section B: REDCap

- **Step 1:** Open the “Safari” web browser



- **Step 2:** In the address bar, type in and go to “[redcap.nyumc.org](https://redcap.nyumc.org)” which is REDCap (internal)
- **Step 3:** Log in to “REDCap (internal)” with your Kerberos ID

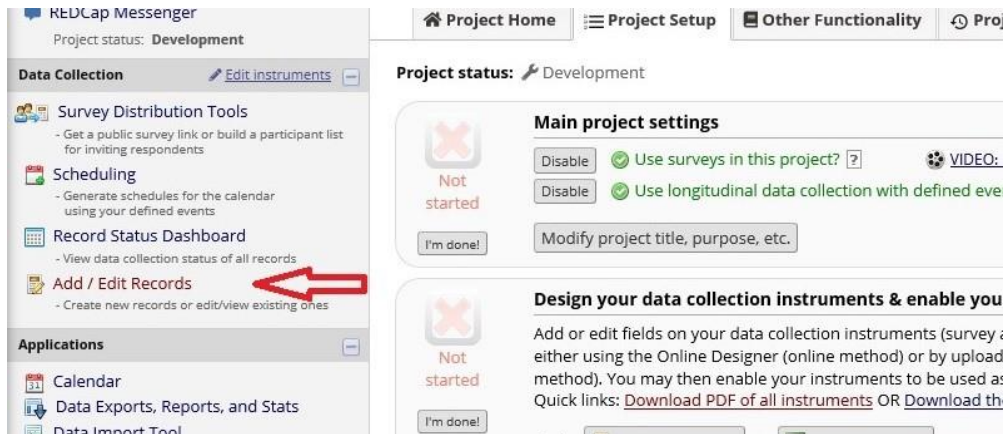
A screenshot of the REDCap login page. At the top left is the REDCap logo. Below it is a 'Log In' button. To the right is a link for 'NYU Langone Health'. The main banner features the NYU HHC CTSI logo and the text 'CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE'. Below the banner, it says 'Welcome to REDCap Internal' and 'Create your account right here on REDCap Internal using your Kerberos ID and password.' There is a note: 'Please log in with your user name and password. If you are having trouble logging in, please contact REDCap Admin.' Below this are input fields for 'Username:' and 'Password:'. At the bottom are 'Log In' and 'Forgot your password?' buttons.

- **Step 4:** Under “My Projects”, click on the project title:  
“Randomized trial of community health worker-led decision coaching to promote shared decision making for prostate cancer screening among Black male patients” for greater study

- Click on “BASELINE” for Baseline part of study only (~20 patients)

## Section C: Entering Survey Mode in REDCap

- **Step 1:** On the left hand navigation menu, under the “Data Collection” heading, click on “**Add / Edit Records**”



- **Step 2:** Select the appropriate research arm that survey/data will be entered for

**Randomized trial of community health worker-led decision coaching to promote shared decision making for prostate cancer screening among Black male patients and their providers**

**Add / Edit Records**

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.

**NOTICE:** This project is currently in Development status. **Real data should NOT be entered** until the project has been moved to Production status.

Total records: **30**

Choose an existing Study ID

Arm 1: Patients A	-- select record --
Arm 2: Patients B	
Arm 3: Providers A	
Arm 4: Providers B	

Data Search

- Arm 1: Patients A
    - Patients in the decision aid intervention group
  - Arm 2: Patients B
    - Patients in the control group (Life's Simple 7)
  - Arm 3: Providers A
    - Providers seeing patients in the decision aid (DA) intervention group
  - Arm 4: Providers B
    - Providers seeing patients in the control group (Life's Simple 7)
  - Baseline Study- skip to next step
    - No selection possible as baseline is the only arm in that REDCap project
- **Step 3:** After selecting the appropriate research arm in Step 2:

- A. If new patient/provider entry record, click “**Add new record for the arm selected above**”

**Add / Edit Records**

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.

**NOTICE:** This project is currently in Development status. **Real data should NOT be entered** until the project has been moved to Production status.

Total records: 15

Choose an existing Study ID: Arm 2: Providers DA -- select record --

**Add new record for the arm selected above** (highlighted with a red arrow)

Data Search

Choose a field to search (excludes multiple choice fields): All fields

- B. If editing or adding to already created record (e.g. next study time point – Post Coaching, Post-Appointment, 6 Month Follow Up), click on “**select record**” and choose the correct “study id” number from the dropdown menu

**Add / Edit Records**

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.

**NOTICE:** This project is currently in Development status. **Real data should NOT be entered** until the project has been moved to Production status.

Total records: 15

Choose an existing Study ID: Arm 2: Providers DA -- select record -- (highlighted with a red arrow)

**Add new record for the arm selected above**

Data Search

Choose a field to search (excludes multiple choice fields): All fields

- **Step 4:** Select the appropriate survey by clicking on first gray bubble in the column for the time point that data will be entered:
  - **Patient Time Points:**
    - Pre-Coaching Survey: click on “Patient Demographics”
    - Post-Coaching Survey: click on “Pre-Decision Preference Shared Decision Making”
    - Post-Appointment Survey: click on “Post-Decision Preference Shared Decision Making”
    - 6 Month Follow Up: click on “Decisional Conflict Scale Post Decision”



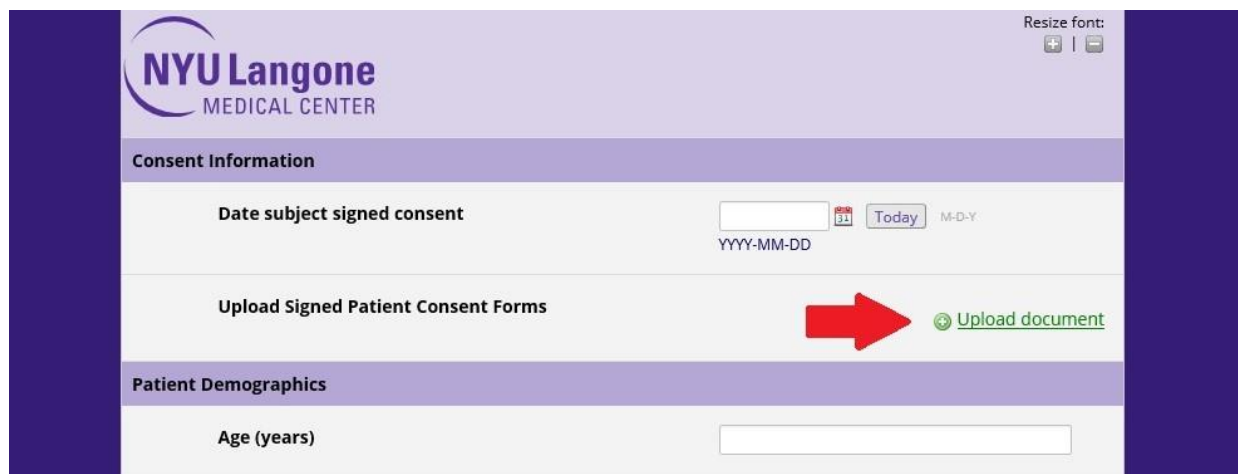
- **Provider Time Points:**
  - Provider Initiation: click on “Provider Demographics”
  - Provider Post encounter: click on “Physician Satisfaction Scale”
  - Provider Completion: click on “Evidence-Based Practice Attitude Scale”
- **Step 5: Switching to survey mode**
  1. If it is a new patient/provider record entry, first click on “Save & Stay” button in the upper right hand corner of the page (skip if editing/adding to already created record)
    - a. Clicking “Save & Exit Form” is also another option, but you will exit the form and must click on the now red bubble to open the form to proceed to the next steps

2. Switch to survey mode by:
  - a. Clicking on the “Survey options” dropdown menu and then “Open survey”
    - i. \*\*\*“Survey options” will not appear if record was not created\*\*\*
      - Click on “Save & Stay” if survey options are not present

## Section D: Uploading Consent Form and Entering Data

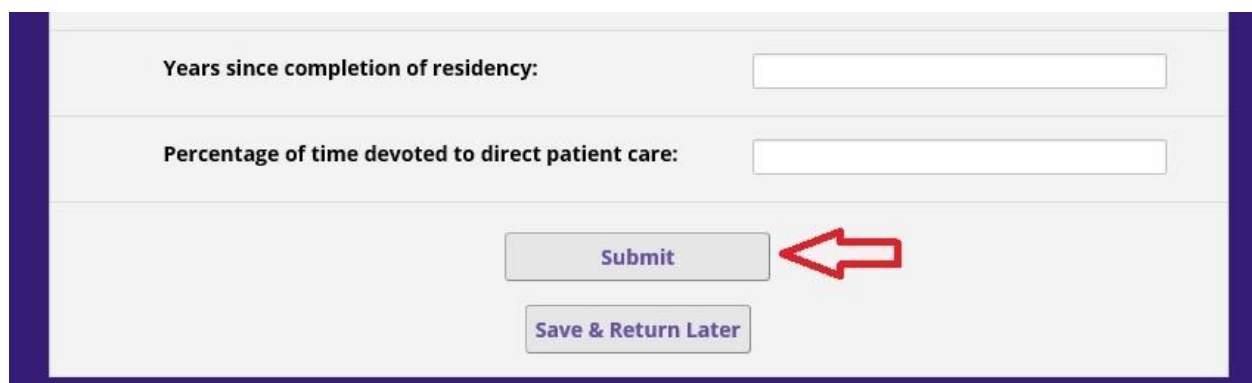


- **Step 1: \*\*\*Data should only be entered in survey mode\*\*\***
  - Survey mode is in NYU purple color scheme without any survey titles on top
- **Step 2: Upload Consent form to REDCap (only during Patient Pre-Coaching and Provider Initiation)**
  - In the Demographics section,
    - Click on the link “Upload document” for the appropriate consent form
    - Click “Choose File”
    - Click on the name of the signed consent file
    - Then click “Upload document”
      - REDCap will acknowledge that the file was successfully uploaded and the patient’s signed consent form file name will be listed in that section



The screenshot shows the NYU Langone Medical Center REDCap interface. The top header is purple with the NYU Langone Medical Center logo. Below the header is a section titled 'Consent Information'. It contains a date field for 'Date subject signed consent' with a calendar icon and a 'Today' button. Below this is a section titled 'Upload Signed Patient Consent Forms' with a red arrow pointing to a green 'Upload document' link. Below this is a section titled 'Patient Demographics' with a text field for 'Age (years)'.

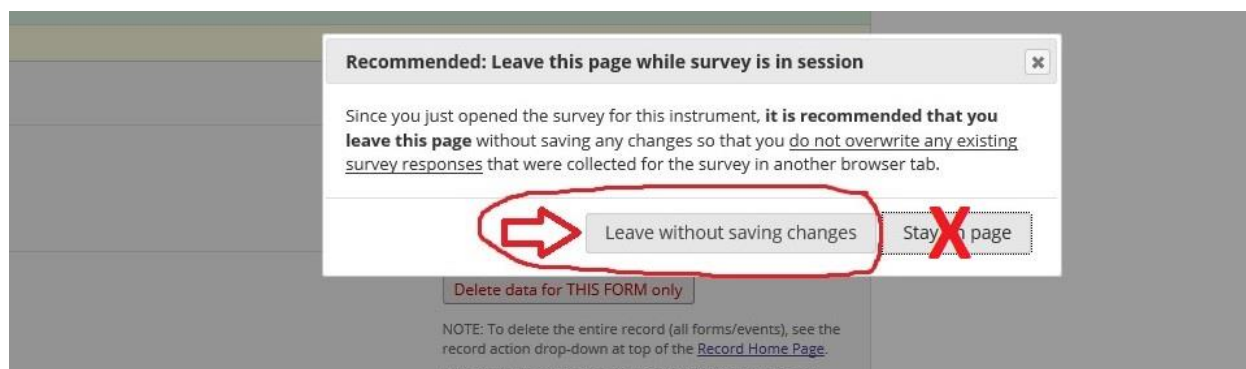
- **Step 3: Continue filling out the Demographics survey**
- **Step 4: Once data entry is complete for the scale, click on “Submit” at the bottom of the page**



The screenshot shows the 'Patient Demographics' section of the REDCap interface. It contains two text fields: 'Years since completion of residency:' and 'Percentage of time devoted to direct patient care:'. Below these fields are two buttons: 'Submit' and 'Save & Return Later'. A red arrow points to the 'Submit' button.

- When you click on “Submit”, the next scale in the survey time point will automatically open up until all scales in the survey time point are complete.
- The final question for all survey time points is “CHW Initials”
  - Click on your name from the dropdown menu and click on “Submit”

- **Step 5: Exiting the survey**
  - Click on “**Close survey**” from the Thank you for taking the survey page
    - **\*\*\*When popup appears, click on “Leave without saving changes”\*\*\***
      - **\*\*\*All data entered in survey mode will be lost if you click “Stay on page”\*\*\***



## Section E: Confirm Data and Consent Forms Recorded

- **Step 1: Confirm data was saved**
  - If the completed survey was submitted and recorded, green check marks will appear next to each scale in the survey

### **Record Home Page**

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

[Choose action for record](#)

**Legend for status icons:**

- Incomplete
- Unverified
- Complete
- Many statuses (mixed)
- Incomplete (no data saved)
- Partial Survey Response
- Completed Survey Response
- Many statuses (all same)

Study ID 40  
Arm 2: Providers DA

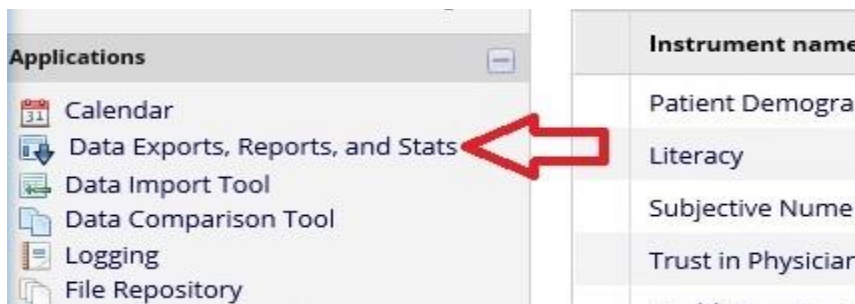
Data Collection Instrument	+ Add new Provider Initiation	+ Add new Provider Post Encounter	+ Add new Provider Completion
Provider Demographics (survey)			
Evidence-Based Practice Attitude Scale (survey)			
Physician Satisfaction Scale (survey)			
Provider Difficulty- Mental Work-Load Instrument (survey)			
Communication Scale Provider- Questionnaire Concerning the Doctor-Patient Communication Skills (survey)			
CHW Initials (survey)			

- Surveys labeled “RESEARCH TEAM ONLY” should be completed at the office only (not with patient/provider)
- **Step 2: After all data was entered and confirmed, user can log out of REDCap**
  - User will be logged out of REDCap automatically after a certain period of time
- **Step 3: Before leaving clinic:**
  - **\*\*\*Confirm with RDA that signed consent form was received before leaving clinic\*\*\***
  - Delete signed consent form from device
    1. Click the Home button and open “Adobe Acrobat” and navigate to “Files”

2. In files, click on the ellipsis (...) next to the file name of the consent form and then click **“Delete”**
  - File will be deleted from iPad
3. **\*\*\*PHI data should never be saved on device\*\*\***

## **Section F: Exporting Survey Data (for RDA & Research Project Manager)**

- **Step 1:** In REDCap (internal), on the left side navigation menu, click on **“Data Exports, Reports, and Stats”** under the Applications heading



- **Step 2:** Under the “My Reports & Exports” tab, click on “Export Data”
  - All exported data must be de-identified
  - The following de-identification options must be selected:
    1. Remove all tagged Identifier fields
    2. Shift all dates by value between 0 and 364 days
    3. Also shift all survey completion timestamps by value between 0 and 364 days
    4. Export survey identifier field and survey timestamp field(s)?
- **Step 3:** Choose export format **“CSV/Microsoft Excel (labels)”** and then click on **“Export Data”**
- **Step 4:** Click on the CSV icon to download the data and save to computer
- **Step 5:** Edit CSV to include only total scores and individual variables needed for data analysis
  - Excel sheet titled “Scales and Scoring for Analysis” will list all data labels that should be included for data analysis
    1. The following labels must be renamed for data analysis:

Scale	Exported Label	Rename Label to
Patient Demographics	if selected other, please specify:	Patient other race
Provider Demographics	if selected other, please specify:	Provider other race
Urology Referral & Screening	If you selected "other", please specify	Urology referral other reason
Pre-Decision Preference for Shared Decision Making	Please choose the ONE statement that best applies	Patient preferred role in decision making
Post-Decision Preference for Shared Decision Making	Please choose the ONE statement that best applies	patient role in decision making during appointment

Post-Decision Preference for Shared Decision Making	Please choose the ONE statement that best applies	patient involvement in screening decision
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## **Section G: Emailing Exported Data (for RDA & Research Project Manager)**

- If emailed, exported data must be de-identified and sent securely
  - The subject line must include the following:
    - [SAFE] – at end of subject line to secure email
    - Grant number (R01...)
    - Study title