

WF-1901: Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)

Helpful Guide



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I. Training

Below are the required training certifications for the WF-1901 IMPACTS study. Please refer to Section 6.6 of the protocol. Each participating site is required to have at least one staff member who is trained and certified for painTRAINER®.

a. painTRAINER® Certification

PainTRAINER® certified staff will support participants who are randomized to the intervention arm of the study, in which participants will use the painTRAINER® program. Staff will be trained using an online training module which can be accessed on the Wake NCORP website; <https://wakencorp.phs.wakehealth.edu/>. Once logged in, staff should navigate to **Studies/WF1901-IMPACTS/ Training → 2020.09.11-WF1901 IMPACTS-painTRAINER training**. The module includes two parts.

- Part I provides an overview of the IMPACTS study, pain coping skills training, and painTRAINER.
- Part II describes procedures for introducing participants to the program and registering them to use it.

Site staff who complete the online training module will receive a score sheet at the end of the presentation. **This score sheet should be printed as a pdf and emailed to NCORP@wakehealth.edu for documentation of completion.** Wake Forest NCORP Research Base will issue a certificate and upload it for you into CTSU to fulfil the person-specific protocol requirement.

Other useful information the study provides for staff and participants:

- ***painTRAINER Introduction and Registration Guide.***
- ***painTRAINER Participant Workbook***
- ***painTRAINER Participant Guide***
- ***other sections of this document***

II. DNA Specimen Collection

a. Initial Specimen Kit Request Process

An *Initial Supply Request Form* will be provided in your start-up packet from WF NCORP RB. Please return the completed form to NCORP@wakehealth.edu to request your initial kit. This form is only to be used for the initial kit request for each local NCORP site. In the future, when additional kits are needed, please see the electronic request process below.

b. Additional Specimen Kit Request Process

Once the initial kits has been assigned to a participant, sites should complete a request for additional kits using the link below. Please choose the WF-1901 study in your request to ensure you get the proper kit.

[WF1901-IMPACTS Supply Request Form](#)

Upon receiving the kits, open each kit, remove ONLY the gel packs and place them in a freezer (-20°C) to be sure they are frozen before shipment. Leave the blood collection tubes in the original box until needed.

Do not remove the blood tubes from the shipping boxes until they will be used to collect blood. Each tube is pre-labeled with the same Kit ID number and the pair of tubes must be returned to the NCORP Biospecimen Lab in the shipping box labeled with the same Kit ID number.

If you have any questions or problems regarding the study, please email NCORP@wakehealth.edu

Contents of Each Specimen Kit

- 1) One BD red top 6 ml Si coated tube with BD Hemogard™ closure (#367815)
- 2) One PAXgene Blood DNA tube (#761115)
- 3) Two Butterfly needle set for vacutainers for venipuncture
- 4) One pre-paid return shipping label
- 5) Packing instructions and supplies for shipment of specimens to Wake Forest NCORP Biospecimen Lab

Sites will need to provide:

- 1) Packaging tape
- 2) Additional venipuncture supplies not provided in the kit as needed.

c. Collection of Blood for DNA

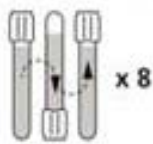
***** Upon receiving the kits, place the gel packs in freezer so they will be frozen BEFORE shipment. *****

- 1) Collect blood in the red top tube first (fill at least half the tube) –this is a pre-draw and the tube and contents should be disposed of but **do not dispose of it in front of the participant.**
- 2) Then collect blood in the PAXgene DNA tube WF-1901 Specimen Kit. **Fill the tube as much as possible.**
- 3) It is **very important to use a butterfly needle set for the PAXgene vacutainers** and to follow the steps below to avoid possible backflow of the chemical additive from the tubes.

- Place participant’s arm in a downward position.
- Hold tube with the stopper uppermost.
- Release tourniquet as soon as blood starts to flow into tube.
- Make sure tube additives do not touch stopper or non-patient end of the needle during venipuncture.



- 4) Upon removal from vacutainer holder, it is very important to **immediately invert the PAXgene tube gently 8-10 times** to mix the blood with the anti-coagulant.
- 5) **DO NOT** centrifuge the sample.
- 6) **DO NOT FREEZE** the blood.



- 7) Dispose the red top tube (NOT in front of the patient).
- 8) The sample may be stored in a refrigerator (4°C) for up to 4 days before shipping (*e.g.* over the weekend). If you draw the blood on Thursday, the tube should be stored in a refrigerator and shipped on the following Monday.

Each tube should be labeled with the following information:

Example: **PID:** _____ **Date:** _____ **Time:** _____

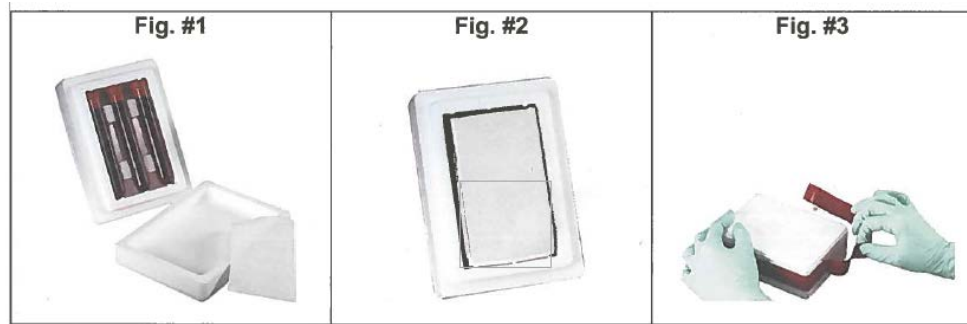
| Test Name | Tube Type | Centrifuge | Specimen Temp | Ship |
|----------------------|-------------|------------|---------------|----------|
| DNA, Telomere length | PAXgene DNA | No | 4°C | ≤ 4 days |

d. Assembly Instructions for Human Exempt Substances

*******Read all instructions thoroughly before starting assembly*******

Assembly Procedure:

- 1) Retrieve a frozen ice gel pack from the freezer where it was placed upon arrival of the specimen kit.
- 2) Place the PAXgene DNA blood tube into the body of the foam mailer (Fig. #1) and cover the tube with the white absorbent material (Fig. #2).
- 3) Firmly press the lid of the foam mailer over the bottom of the mailer containing the blood tube and absorbent material until all sides of the lid meet the sides of the body.
- 4) Peel the white backing from the provided red waterproof tape and seal the foam mailer by completely covering the joint between the lid and body. The ends of the red tape should overlap about an inch (Fig. #3). Enclose the sealed foam mailer in the press-lock biohazard bag.
- 5) Fold the COMPLETED ***Blood for DNA Collection Form*** and place it on the bottom of the small cardboard shipping box under the closed biohazard bag containing the foam mailer.
- 6) Place the frozen ice gel pack on top of the sealed biohazard bag and seal the shipping box with package sealing tape (not supplied) over the locking tabs. Note: the ***Blood for DNA Collection Form*** should NOT be in contact with the frozen ice brick.
- 7) Fill out the “From” section of the pre-addressed “Peel-and-Stick FedEx Express Package US Airbill.” Be sure to include your telephone number. Then peel the back off of the FedEx label and wrap it around the outside of the box for mailing. Be careful to not cover the labels on the ends of the shipping box.



e. Shipment of Blood for DNA

- 1) Samples should be shipped by FedEx priority overnight on **Monday, Tuesday or Wednesday only.**
- 2) Samples should be shipped in the containers provided with the frozen gel pack provided in the specimen kit. **Blood must NOT be frozen.**
- 3) Follow the guide on the previous page for “*Assembly Instructions for Human Exempt Substances.*”
- 4) Be sure to enclose the completed “*Blood for DNA Collection*” form.
- 5) Pack the tubes as described in the “*Assembly Instructions for Human Exempt Substances*” on the previous page. The pre-paid shipping label has an adhesive back that should be used to attach it to the shipping box; carefully wrap the label around the box such that the address information is on top and does not cover the labels on the ends of the shipper.

ATTN: WF-1901 IMPACTS
WF NCORP Biospecimen Lab
Bldg. A1A Lab 230 c/o Delivery on Time
Wake Forest School of Medicine
Richard Dean Bldg. Receiving Dock
391 Technology Way
Winston-Salem, NC 27101
Phone: (336) 716-2581

- 6) Notify WF NCORP RB **before** the sample is shipped by completing the *Blood for DNA Collection Form* in REDCap. By completing this form, an email will be sent to the WF NCORP Biospecimen Lab automatically as an alert of the shipment.
- 7) **NOTE:** Site must comply with Shipping and Handling Instructions compliant with International Air Transport Association (IATA) Dangerous Goods Regulations. The shipping box is pre-labeled with the proper labels for compliance with IATA shipping regulations.

f. Blood for DNA Shipping Form

INSTRUCTIONS:

- 1) Send a completed copy of this page along with specimen samples to WF NCORP Biospecimen Lab
- 2) Place the original in the patient’s protocol chart.
- 3) Log into REDCap and complete the *Blood for DNA Collection Form*.

NOTE: PID, FEDEX Tracking # and Shipping Kit# must be entered into REDCap prior to shipping.

PID: _____

Shipping Kit #: _____

FEDEX Tracking #: _____

Blood Specimen Information:

Timepoint:

BASELINE (T1)

10 WEEK (T2)

Date and time blood sample drawn:

M M

D D

Y Y Y Y

H H

M M (military time)

FOR LAB USE ONLY

| Time Point | Date Received | Tubes Intact (Y/N) | Usable (Y/N) | Date Analyzed |
|--------------|---------------|--------------------|--------------|---------------|
| Baseline | | | | |
| T2 (10 week) | | | | |

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III. Participant Workbooks

a. Initial Workbook Request Process

Participants randomized to the painTRAINER intervention will receive a *painTRAINER Workbook* and a copy of the *NIH Cancer Pain Control Booklet* at randomization.

Participants in the Enhanced Usual Care arm will receive a copy of the *NIH Cancer Pain Control Booklet* at randomization.

A *WF-1901 Initial Supply Request form* will be provided in your start-up packet. Please return the completed form to NCORP@wakehealth.edu to request randomization materials that includes one *painTRAINER+ NIH Cancer Pain Control Booklet Combo* for the painTRAINER arm and one *NIH Cancer Pain Control Booklet* for the Enhanced Usual Care Arm. This form is only to be used for the initial request for each local NCORP site. In the future, when additional workbooks and booklets are needed, please see the electronic request process below.

b. Additional Workbooks Request Process

Once the initial participant has been randomized and one set of materials has been used, sites should complete a request for additional materials using the link below.

[WF1901-IMPACTS Supply Request Form](#)

IV. Tablet Lending Program

a. Overview

Recognizing that Internet-based interventions like this one inherently are limited to individuals with regular and reliable access to the internet, internet-enabled devices, and sufficient data for internet usage, we created a Tablet Lending Program to extend study access to a broader portion of the population that might otherwise be unable to participate. Using the *Internet Access & Tablet Lending Program Screening* questions within the **Screening Interview & Log**, participants meeting study eligibility criteria will be asked whether they have regular and reliable access to the internet through a computer, laptop, tablet, or smartphone device for at least 1 hour each week over the 10 weeks of the intervention period. Those reporting that they do not have such access who are then randomized to the painTRAINER[®] intervention group will be invited to participate in the Tablet Lending Program, to provide those participants with access to a pre-paid Wi-Fi- and cellular-enabled tablet device, with a pre-paid cellular data plan, for the duration of the study intervention.

The IMPACTS Study Team located at Wake Forest School of Medicine (WFSM) will serve as the central repository and distribution center for all tablets involved in the IMPACTS study. All tablets will come from, be returned to, and stored in secure space at WFSM.

The IMPACTS Study Team will be responsible for activating the cellular network on each tablet prior to its distribution to a local NCORP site. All tablets will be formatted with filters on data and internet access. **These filters will limit access to the painTRAINER[®] application to prevent use of the tablet for other purposes.** All existing participant information remaining on the tablet after use will be removed prior to it being provided to another site.

Tablets will be shipped to the site after completion of the **Tablet Request** form within the **WF-1901-IMPACTS-Tablet Lending Program** project in REDCap[®]. The site will sanitize the tablet using the directions and supplies provided. If the participant is randomized to the painTRAINER[®] intervention, orient the participant to the tablet and painTRAINER[®], and review the instructions for tablet care and return upon intervention completion. **Remember that only participants randomized to painTRAINER are eligible for a tablet.**

The participant will be expected to keep the tablet for 10-12 weeks and will return the tablet, case, and charging cable/cube to the local NCORP site upon completion of the painTRAINER[®] intervention. Sites will return the tablet and charging cord/cube to the IMPACTS study team using mailing supplies provided by the study team, after cleaning using the supplies and directions provided.

For those participants completing study visits virtually, the tablet may be shipped directly to the participant's preferred address and a remote tutorial will be scheduled. The participant's shipping address should be entered into the **Tablet Request** form along with a comment including the participant's name and note that it was sent directly to this participant. At completion of the 10-week intervention period, participants will be asked to return the tablet using a pre-paid return-addressed shipping container provided to them in the initial tablet shipment.

b. Instructions On Using The Program

1) REQUESTING A TABLET

When an eligible participant is screened, using the *Screening Interview & Log* found in the **WF1901-IMPACTS-Screening** REDCap® project, and indicates that a tablet will be needed, you will be informed to go to the *Tablet Request* form in REDCap®.

On the *Tablet Request* form in the **WF1901-IMPACTS-Tablet Lending Program** REDCap® project, you will be required to enter the reason for providing the tablet, and the appropriate shipping information where the tablet is to be received. There is also a box to indicate that you already have a tablet onsite that can be used for this participant and to provide the serial number of the onsite tablet.

2) SHIPPING AND TRACKING PROCEDURES

After your *Tablet Request* form is received, please allow at least five (5) business days for the tablet to be shipped to your site. You should allow for a minimum of one week between screening and baseline so that the tablet arrives prior to the baseline visit. You will receive an email confirmation that the tablet has been shipped containing the tracking information of the shipment.

When you receive the tablet, please 1) indicate on the *Tablet Received by Site* form in REDCap that the tablet has been received and 2) return the *Initial Chain of Custody Tracking* document electronically to WF NCORP RB at NCORP@wakehealth.edu.

3) TABLET SANITATION PROCEDURES

The tablet you receive from the IMPACTS study will be thoroughly sanitized before it is sent to you. For safety purposes, it is your responsibility to clean the tablet again using the supplies provided in the shipping container. In addition to the tablet/case and IMPACTS participant packet containing gloves, wipes, earbuds, charging cable, and adaptor, we will provide you with several sets of disinfecting wipes so that you can clean the tablet prior to providing it to the participant, when it is returned to you and before it is returned to the IMPACTS study team.

To prepare a tablet prior to participant orientation, you will need to complete the following steps:

- When you receive the shipment from the IMPACTS study team, confirm that the tablet (in case), charging cable and adaptor, participant packet, disinfecting wipes, chain of custody documentation, and return mailing supplies are enclosed.
- Retain the box, bubble wrap, and air packs in order to return the tablet.
- Power on the tablet to make sure it is working. Charge if needed.
- Open the internet browser to make sure the cellular connection is working.
- Clean the tablet using one packet of the disinfecting wipes provided:
 - Put on disposable gloves.
 - Remove the tablet from the case and wipe down exterior of tablet, focusing on screen and home button. Wipe tablet down three times, each time with a new wipe. Dispose of wipes.
 - Wipe down interior and exterior of case, paying special attention to the sides where it is held. Wipe down three times, each time with a new wipe. Dispose of wipes.
 - Wipe down charging cube and the length of the charging cable.
 - Allow tablet and case to dry before placing tablet in case.

Instructions and a script for painTRAINER® registration and orientation have been provided in the *painTRAINER® Introduction and Registration Guide* document found on CTSU. In addition to introducing the participant to painTRAINER® and providing instructions on how to use it, you should review the basics of operating the tablet with the participant. Review the location of the power and sound buttons, the process for turning it on/off, and how to charge the tablet.

4) **PARTICIPANT TABLET RETURN**

Participants are expected to return the tablet, case, charging cable, and adaptor to the local NCORP site at the T2 visit unless arrangements have been made to send the tablet directly to the participant. In this case, the participant will have supplies to return the tablet. When a participant has completed six of eight required painTRAINER® modules, you will receive a reminder from the NCORP Research Base to contact the participant and remind him/her about their upcoming visit and that they will be required to return the tablet at that time.

If a tablet is not returned at the T2 visit, you should arrange for the participant to bring it to the site within one week. If the tablet has not been returned after one week, please contact the participant and remind him/her to return delinquent tablet. If the participant indicates they cannot return to the site, please contact NCORP@wakehealth.edu and a pre-paid mailer will be sent to the participant directly. You can also request a pre-paid mailer be sent to the participant using the *Lost or Damaged Tablet* form. The pre-paid mailer will be addressed to the IMPACTS study team. If the tablet is not returned using the pre-paid mailer in the following 30 days, you will report the tablet as a loss to NCORP@wakehealth.edu and you will submit a report to the WF NCORP Research Base using the *Lost or Damaged Tablet* form.

You may have more than one participant during the study who qualifies for the tablet lending program. When a participant for whom you have requested a tablet is not randomized to the painTRAINER arm, your site can choose to hold the tablet for up to 30 days in the likelihood that another participant may be scheduled for a baseline visit who is eligible for the tablet lending program. If you choose to do this, please email NCORP@wakehealth.edu to notify the study. If the tablet is not needed at your site within 30 days, please return it to the IMPACTS study.

When returning a tablet:

- Follow the sanitation procedures described previously before shipping the tablet back to the IMPACTS study team.
- Using the box in which the tablet was shipped to you, wrap the tablet, still in the case, in bubble wrap and use air pack(s) to minimize any extra space in the box.
- Place the charging cable and adaptor, along with the signed Chain of Custody Tracking Return Form (found below), in the box and seal tightly with shipping tape.
- Affix the return shipping label to the exterior of the box. Use the pre-populated, pre-paid FedEx shipping slip provided in the initial shipment.

Notify the IMPACTS study before the tablet is shipped by completing the *Tablet Return Shipping* form in the **WF1901-IMPACTS-Tablet Lending Program** project in REDCap®, including documenting the tracking number on the shipping label. By completing this form, an email will be sent automatically to alert us of the shipment.

5) **TROUBLESHOOTING PROBLEMS WITH TABLETS AND painTRAINER®**

Participants are instructed to contact their local NCORP site if they experience problems using the painTRAINER website or with the tablet. If the local NCORP staff does not have the resources to provide assistance within 5 minutes, they should contact NCORP@wakehealth.edu and the problem will be triaged to the correct person on the IMPACTS or painTRAINER® teams. More information on troubleshooting problems with participants and referring more complex problems to the IMPACTS study team can be found in the painTRAINER Section of this document, Part C Technical Support Procedures for Local NCORP Sites.

6) **DAMAGED OR LOST TABLETS**

When a participant reports damaging or losing a tablet that was issued through the tablet lending program, please complete the *Lost or Damaged Tablet* form in the **WF1901-IMPACTS-Tablet Lending Program** project in REDCap® to report this to the IMPACTS study team. If a participant fails to return a tablet after they have completed the painTRAINER® program and does not mail it back to the study as described previously, this form should also be completed.

WF NCORP Research Base WF-1901

Chain of Custody Tracking Return Form

Upon shipping supplies back to Wake Forest NCORP Research Base, please print a copy of this form for your sites records, send a copy with the shipment and email a copy to:

Wake Forest NCORP Research Base
 Attn: IMPACTS Study Team (WF-1901)
 Email: NCORP@wakehealth.edu

| | |
|---|---|
| Study Item Description | Apple iPad (10.2-Inch, Wi-Fi + Cellular, 32GB) with charging cable & adaptor Serial: Quantity Shipped: 1 |
| Name, Address and Phone number of Releasing Organization | |
| Person completing form | |

| | |
|-------------------------------------|--|
| Method of transfer | Fed Ex via pre-populated, pre-paid shipping slip |
| Date study items are shipped | |

| | | | |
|---|---|---|--|
| Name, Address and phone number of receiving organization | Wake Forest Baptist Medical Center Wake Forest NCORP Research Base 525@Vine, 4 th floor Medical Center Blvd Winston-Salem, N.C. 27157 Phone: 336-716-0891 | | |
| Recipient Name and date | | Person verifying receipt Name and date | |

c. Using the Tablet

A copy of the information on this page will be provided with each tablet (e.g. Apple iPad) for the participant use.



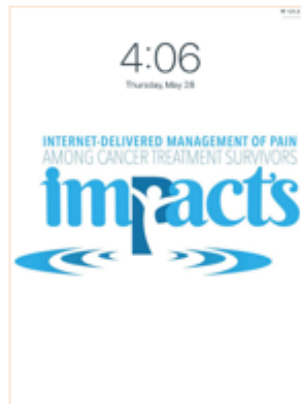
Turning on the iPad

Hold the POWER button down until the screen lights up. You will see the Apple logo appear in the middle of the screen. After the iPad powers on, you will see the lock screen to your right.

To open the iPad, press the HOME button. This will allow you to access the painTRAINER® website.

Controlling the Sound and Volume

To adjust the volume, use the VOLUME buttons on the left side of the iPad. If there is no sound, try flipping the MUTE switch on the side of the iPad and trying again.



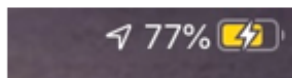
How to charge the iPad



In the top right corner of the screen, you will see a small image of a battery with a percentage above it. This will let you know how much battery power the iPad has left.

A cable and charging adaptor were included with your iPad. When the iPad needs to be charged, plug the large end of the cable into the charging adaptor and then plug the charging adaptor into an electrical outlet. Find the CHARGING PORT on the bottom edge of the iPad. Plug the small end of the cable into the charging port.

If the iPad still had power when you begin charging, you will see a lightning symbol inside of the battery symbol in the top right corner. If the lightning symbol is not there in the battery, the iPad is not charging.



If the iPad is charged properly and had no battery life, the low battery symbol will appear in the center of the screen if the iPad is charging properly.

If you are having problems using your iPad, please contact your study contact person listed on the back of your painTRAINER® Workbook.

V. Medication Diaries

Please follow the instructions below to complete the staff portion of the patient’s **7- Day Medication Diary**. The **7-Day Medication Diary** form was intended to be completed as a paper form. The first page of the form includes an example for how to fill-in and complete the form. The second page of the form can be duplicated once you have completed the patient study header to provide additional space for patients to record their medication information. Make sure you also add page numbers to each page that you are providing to the patient.

a. For T1 and T2 Visits:

- 1) Please complete, **for the patient**, the **Medication**, **Type** and **Dose/Strength** fields on the form for any medication that the participant currently is taking, using the medical record to provide a complete list of all medications. Please provide additional blank pages for medications, supplements, or essential oils that the participant may need to add at home later.

| | | | | | | |
|-------------------------|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Medication | <i>Norco (hydrocodone acetaminophen & bitaltrate)</i> | | | | | |
| Type | Pill | Liquid | Inhaled | Patch | Injection | Other |
| | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Dose or Strength | <i>70mg/325mg per tablet</i> | | | | | |

- 2) Review the medications with the patient. For each medication, ask them if they take the medication for pain AND ask the additional two Typical Medical Usage questions.

| | | |
|-------------------------------------|---|-----------------------------|
| Do you take this medicine for pain? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
|-------------------------------------|---|-----------------------------|

AND

| |
|--|
| On a typical day, how much of this medication do you typically take? [Record number of doses taken during a typical 24 hour period] [Staff only] |
| <i>Typically takes 3 pills per day on a typical day (1 pill or a single dose every 4 hours during the day time)</i> |
| “What do you typically take this medication for?” [Staff only] |
| <i>Typically takes this med to help manage pain on days when pain level is high</i> |

- 3) Review with the patient how they should complete the diary over the next 7-days at home.

| For each day (from Midnight to Midnight) record how much you took of each of your medicines (Pill counts, number of puffs, dropper mgs, etc) | | | | | | |
|--|----------|----------------|----------------|----------|----------------|-----------------|
| Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
| <i>3 pills</i> | <i>0</i> | <i>5 pills</i> | <i>2 pills</i> | <i>0</i> | <i>3 pills</i> | <i>1/2 pill</i> |

- 4) Review with the patient how they should rate their pain **each day** at the top of the first page.

| 7 Day Medication Diary & Typical Usage | | Please enter the date for each day of the week: | | | | | | |
|---|--|---|-------------|-------------|-------------|-------------|-------------|-------------|
| EXAMPLE | | ___/___/___ | ___/___/___ | ___/___/___ | ___/___/___ | ___/___/___ | ___/___/___ | ___/___/___ |
| On a scale from 0 to 10, with 0 meaning "no pain at all" and 10 meaning the "worst pain ever," please rate the HIGHEST level of pain you experienced each day. Record your ratings here → | | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
| | | 7 | 2 | 9 | 5 | 2 | 7 | 3 |

- 5) Ensure that all pages have the patient header and page numbers completed. Make a copy of the form for the patient to take home. **You keep the original as a source document for the Typical Usage portion.**
- 6) Give the patient the **patient instructions** with the **example page**, as well as a copy of all pages and a pre-paid return envelope provided by the IMPACTS study. Instruct patients to return the **7-Day Medication Diary** directly to the Wake Forest NCORP Research Base.

b. For T3 and T4 Visits:

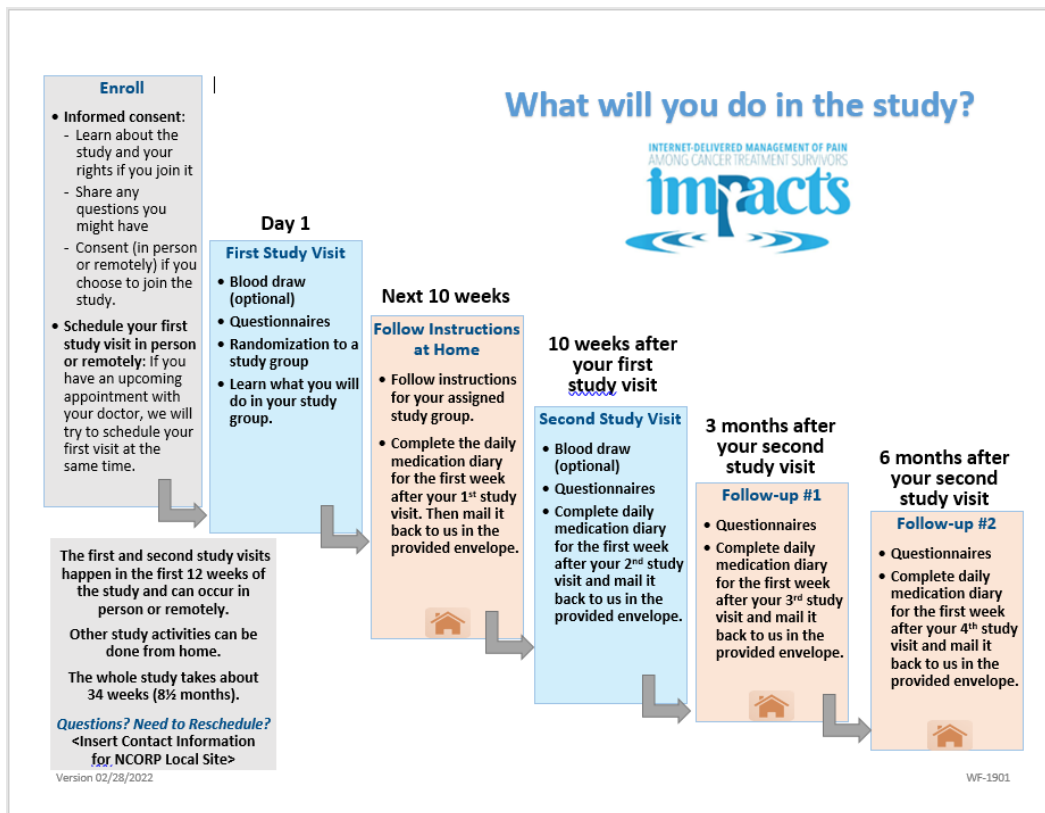
****If your participant has noted at screening the need to receive a loaner tablet through the Tablet Loaner Program, or if you think they may not have access to their email to complete the T3 or T4 survey, please call them to confirm if they will need a paper version of the survey mailed with their **7-Day Medication Diary**. It is recommended to make this call at 20 and 32 weeks, in order to get the documents in the mail by 21 and 33 weeks (ahead of the 22 and 34 week assessment timepoints).

- 1) Please complete for the patient the **Medication, Type and Dose/Strength** fields on the form for any medication that the participant currently is taking, using the medical record to provide a complete list of all medications. Please provide additional blank pages for medications, supplements or essential oils that the participant may need to add at home later.

| | | | | | | |
|-------------------------|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Medication | <i>Norco (hydrocodone acetaminophen & bitaltriste)</i> | | | | | |
| Type | Pill | Liquid | Inhaled | Patch | Injection | Other |
| | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Dose or Strength | <i>10mg/325mg per tablet</i> | | | | | |

- 2) **The patient will not do the two typical usage questions for these time points (T3 and T4).** They are designated as "Staff Only", so the patient will not complete them. However, you may draw a line through them, initial and date these questions, if you prefer.
- 3) Ensure that all pages have the patient header and page numbers completed. We recommend making a copy of the form, in case it gets lost in the mail.

- 4) Give the patient the **patient instructions** with the **example page**, a copy of all pages and a pre-paid return envelope provided by the IMPACTS study. Instruct patients to return the **7-Day Medication Diary** directly to the Wake Forest NCORP Research Base.
- 5) These **7-Day Medication Diaries** should be mailed for T3 at week 21 and T4 at week 33. Additionally, include a paper survey if the patient is unable to use the email survey. We would prefer that patients complete surveys through the email link, as the logic is much easier to follow.
- 6) Per protocol, you are asked to talk to the patient in clinic or call to encourage them to complete the survey and diaries at the specified time points. Please refer to the protocol for details. There is a Study Timeline patient handout that can be helpful for keeping the patient on track. This handout can be downloaded from the protocol documents found on the CTSU website.



VI. Baseline (T1) Survey Tips and Tricks

The patient should complete the Baseline (T1) survey before randomization. The questionnaire is designed to be taken as a survey via a tablet or computer. It can be administered on paper, note that answers will have to be entered manually into REDCap® afterwards. Patients will be compensated after the completion of the Baseline Visit.

To trigger the baseline questionnaire to be emailed to the participant prior to their T1 visit, complete the *Additional Visit Questions* form found in the **WF-1901-IMPACTS** project; there is a “Send T1 survey link” field in this form.

Please click here to send T1 survey link to the participant:

This will send the survey link to the participant's email above as soon as this form is saved. Daily reminders will be sent for an additional 5 days or until the participant completes the questionnaires. If the participant has not completed the T1 questionnaires after these reminders end, please verify the participant's email and contact NCORP@wakehealth.edu

Send T1 survey link

reset

To administer the survey electronically in person, you may launch the survey from REDCap® using the following steps.

- 1) Log into REDCap® and then open the **WF1901-IMPACTS** project.
- 2) Select the participant’s PID from the list.
- 3) Choose “Baseline Survey Start” from the T1 column

| Data Collection Instrument | Enrollment | T1 |
|--------------------------------|----------------------------------|-----------------------|
| Eligibility/Enrollment | <input checked="" type="radio"/> | |
| Additional Randomization Info | | <input type="radio"/> |
| Weight and Height | | <input type="radio"/> |
| T2 Email Trigger | | |
| T3 Email Trigger | | |
| T4 Email Trigger | | |
| Contact Attempt Log | | |
| painTRAINER Monitor | | |
| Baseline Survey Start (survey) | | <input type="radio"/> |

- 4) Under Survey Options: Choose “Log out + Open Survey”.

Baseline Survey Start

Data Access Group: [No Assignment] ?

Invitation status: [icon]

Survey options

Open survey

Log out + Open survey

Compose survey invitation

Survey Access Code and QR Code

Editing existing PID 1901000

Event Name: T1

PID 1901000

Dear Participant,

Thank you so much for agreeing to participate in the IMPACTS study!

This study is designed to test two different strategies for managing chronic pain in cancer survivors. As a part of your participation, we are going to ask you a series of questions about your health, health behaviors, and your thoughts, feelings, and emotions.

Please answer questions thinking of your cancer-related pain and not any other pain you may be experiencing today.

Sometimes, it may feel like we are asking you the same questions in different ways. Please do your best to answer all of the questions, even if some feel like they have been repeated.

We appreciate your help!

Sincerely,

The IMPACTS Study Team

Form Status

Complete? Incomplete

- 5) The REDCap system will log you out and the questionnaire will appear on the web browser. The participant can follow the screen prompts to complete the series of questionnaires. This is good practice for doing the surveys via the email link they will receive for T2, T3 and T4.

Baseline Survey Start

Resize font: [icon] [icon]

Dear Participant,

Thank you so much for agreeing to participate in the IMPACTS study!

This study is designed to test two different strategies for managing chronic pain in cancer survivors. As a part of your participation, we are going to ask you a series of questions about your health, health behaviors, and your thoughts, feelings, and emotions.

Please answer questions thinking of your cancer-related pain and not any other pain you may be experiencing today.

Sometimes, it may feel like we are asking you the same questions in different ways. Please do your best to answer all of the questions, even if some feel like they have been repeated.

We appreciate your help!

Sincerely,

The IMPACTS Study Team

Submit

VII. painTRAINER®

a. Participant Introduction and Registration

Using the *painTRAINER® Introduction and Registration Guide* found on the CTSU website under the WF-1901 study, this document will guide you through the following processes with the participant:

1. *Introduce the participant to the program.* The introduction will ensure that participants in the painTRAINER study arm understand what the painTRAINER program is and how they will use it in the study.
2. *Ensure that participants successfully register to use the program.* Registration occurs within the painTRAINER website. Participants will not be able to begin using painTRAINER until after they register. When registering, the participant's PID (1901###) should be entered as their username and they can select a password of their choice.

This guide provides several options through which participants can complete the introduction and registration process:

1. The introduction to the painTRAINER® program can occur either:
 - a. In person at the study site
 - b. Via phone/video conference.
2. Registration can occur either:
 - a. In person at the study site, using the site's internet-enabled device (or, if participant has it with them, they can use their own smartphone or tablet/laptop).
 - b. When participants are at home, they can use their own device to register independently and/or with phone/video conference guidance by site staff.

The introduction and registration scripts within this document should be used with each participant to ensure a consistent introduction and successful registration experience to painTRAINER®.

b. painTRAINER® FAQ and Responses

This section is a resource that will help you respond to questions you may get from study participants randomized to use the painTRAINER® program. Our goals are to:

- *Standardize study team responses to these questions, which optimizes the extent to which all participants have the same information about the program and the study*
- *Ensure that participants completely understand what they will be doing in the study and in the painTRAINER® program*
- *Avoid or minimize participant uncertainty or potential for frustration, which is important for all participants but especially those with little experience working on a computer or mobile device, or little confidence in their ability to do these things.*

We will update this document as we become aware of additional questions that should be included. Please feel free to email NCORP@wakehealth.edu with ideas for additions or changes to this document.

***Participant version of this document:** We have created a version of this document within the painTRAINER® Participant Guide that you can give participants who are randomized to use painTRAINER®. Please remember to write in the name and phone and/or email information for their staff contact person on the back of the painTRAINER® Workbook, when giving them these documents.*

- **What is painTRAINER®?**

Answer: painTRAINER® is a web-based pain coping skills training program that teaches people to use pain coping skills that research has shown can help them reduce their pain and get back to doing activities that are important to them. This training has been delivered in-person in the past. People traveled to attend either one-on-one or small group in-person training sessions over weeks or months. Now painTRAINER® allows you to get this training at home using many of the same training techniques that are used in the in-person training.

- **What will painTRAINER® teach me?**

Answer: In painTRAINER®'s 8 training sessions, you'll learn how thoughts, feelings, and behaviors affect your body's responses to pain, and you'll learn pain coping skills that research has shown can help people reduce their pain and get back to doing activities that are important to them. You'll also learn how to use these skills in your daily life, and how to keep using them after the training ends.

- **What are pain coping skills?**

Answer: Pain coping skills are things you can do to change thoughts, feelings, and behaviors that are related to how much pain you feel and how it affects your ability to do things that are important to you. You can use these skills in your daily life, along with any other pain treatments you are using, to become more involved in your pain management.

- **How will I learn these skills in the painTRAINER® program?**

Answer: You will sign in to the program to complete the program's eight pain coping skills training sessions. We recommend you complete one per week. If you need to delay completing a session for a few days or a week, that's okay. Just start again as soon as you can. We do not recommend completing more than one session per week, because—like any new skill, like riding a bike—it is important to practice new skills you learn between sessions. The sessions are mostly in audio, with animations and graphics. They also include some interactive exercises that help you learn. Most people say they really like how the training is presented. Each session takes 35 to 45 minutes to complete, and you can complete them any day of week and any time of the day or night that is convenient for you.

- **How can skills like this make a difference in my pain?**

Answer: You'll learn all about that in painTRAINER®'s first session. It tells you how certain thoughts, feelings, and behaviors influence how your body's pain signals travel to your brain and, once they reach your brain, the different ways they affect how you feel and experience pain.

- **You mentioned that my thoughts, feelings, and behaviors affect my pain. Does that mean that you think my pain is all in my head?**

Answer: Not at all. We know that pain is real. We also know that a number of things can influence the severity of your pain and how much it affects your ability to do activities. Your thoughts, feelings, and behaviors can actually affect how pain signals from your nerves travel up your spinal cord to your brain. As you practice with pain coping skills you may be able to affect connections among different pain-related areas in your brain.

- **Is there scientific evidence that pain coping skills can help me with my pain?**

Answer: There is. There is scientific evidence supporting the benefits of the individual pain coping skills you'll learn in painTRAINER® in reducing pain. Also, both in-person and web-based pain coping skills training has been tested in randomized controlled trials and shown to reduce pain and pain-related impairment.

- **Am I expected to practice all of the skills?**

Answer: Ultimately, it's really up to you. But pain coping skills are like any skill you learn in life—the more you practice them and use them in your daily life, the better you'll get at using them and the more benefit you'll get from them. The program will give you tips for remembering to practice and suggestions for how much you should practice.

- **Can painTRAINER® help me remember to practice?**

Answer: It can. In the painTRAINER® Progress Tracker you can set up or change reminders to practice the pain coping skills you've learned and to complete the next painTRAINER® session. You can also turn the reminders off. You can change the frequency of practice reminders or turn those reminders off in painTRAINER®'s Progress Tracker (in the "Log Practices" section) or in "My Profile." You can change how you are reminded to complete sessions, or turn off those reminders, under "My Profile."

- **What if I don't like using one or more of the skills?**

Answer: You'll learn seven pain coping skills in painTRAINER® as well as strategies for maintaining the benefits you've gained from learning these skills. It's common for people to use some of the skills more than others. You don't have to use all of them. However, we encourage you to try them all and, if you don't like one, see if you can figure out a way to use it that works for you. Many people use different skills in different situations. They're like tools in a toolbox. The more skills you have worked with, the more likely you'll be to find the right tool to use in different situations.

- **What if I find the program is too hard to use?**

Answer: The program was designed to be very easy to use. We've had people use it who have rarely or never used a computer or a web-based program. If you need help, you can call us or ask a family member or friend for help.

- **Can I complete the painTRAINER® sessions more quickly than one per week?**

Answer: We do not recommend completing more than one session per week, because—like any new skill, like riding a bike—it is important to practice new skills you learn between sessions.

- **What if things come up and I can't complete one session per week?**

Answer: If you need to delay completing a session for a few days or a week, that's okay. Just start again as soon as you can.

- **Will I be able to skip a session?**

Answer: You won't be able to skip a session because each session builds upon the one before it. Also, it's good to learn all of the skills because many people use different skills in different situations. They're like tools in a toolbox. The more skills you have worked with, the more likely you'll be to find the right tool to use in different situations.

- **What if I can't finish the program?**

Answer: This is a voluntary research study and you are free to stop using the program at any time you wish. If you decide you need to do that, just contact [staff contact person's name and contact information] so that we know.

- **If I have to step away from a session and come back later, will painTRAINER® save my place?**

Answer: Yes, it will.

- **Will I have access to sessions I have already finished?**

Answer: You will. You can go back to sessions you've already finished at any time during the study, and even use the session's toolbox to go back to separate parts of the session, such as instructions for using or practicing a skill.

- **After I complete painTRAINER®, will I still have access to it if I want to do one of the sessions again?**

Answer: You'll be able to use painTRAINER® as long as you are in the study.

- **What are the session toolboxes?**

Answer: These are links that give you quick access to parts of a painTRAINER® session you have completed, but that you may want to revisit—for instance, a description of a pain coping skill or instructions for using and practicing it. You can revisit them without having to do the entire session over again. Most of the painTRAINER® sessions have a toolbox that will appear once you have completed a session.

- **Can I still take my normal medications while using painTRAINER®?**

Answer: Yes. Keep doing the things that you and your healthcare team decide are right for you.

- **Will my pain management regimen affect how well painTRAINER® will work for me?**

Answer: Research shows that pain coping skills work for people using many kinds of pain management strategies.

- **Will I be able to get rid of my pain if I use these skills?**

Answer: Pain coping skills can help you reduce your pain and get back to doing activities that are important and meaningful for you. Very few people report that these skills eliminate their pain. However, people who use this program often report noticeable, meaningful changes in their pain and an improved ability to do activities.

- **Can I share painTRAINER® with someone else? My partner/family member/friend has pain too...**

Answer: Please don't allow anyone to sign on to the program with your username and password. If you know someone who wants to use the program, we ask that they wait until you finish the study. That will help us make sure the study is as strong as possible so that the findings can be used to help people like you. After you finish the study, just reach out to your local study contact person and we will provide instructions for your friends and family to get access.

- **What if I forget my username or password?**

Answer: Your username will be written on the back of your painTRAINER® workbook. Also, the webpage where you sign into painTRAINER® allows you to recover your username and your password if you forget them. It's very easy to do.

- **How much time should I set aside for completing painTRAINER® sessions?**

Answer: You'll do one painTRAINER® session per week, and each one takes 35 to 45 minutes to complete.

- **How much time should I set aside for practicing painTRAINER® skills?**

Answer: Regular practice will help you get the most benefit possible out of the program. The more you practice the more you will benefit. All in all, it may take up to 20 or 30 minutes most days a week, and no time or just a few minutes other days. You'll choose the timing of your practices so they are convenient for you.

- **Who should I contact if I can't get on the program, or if I'm having technical difficulties?**

Answer: First, take a look at the section called "Devices and Technical Questions" within the *painTRAINER® Participant Guide*. You may find that it answers a question you have or helps you solve a problem. If not, you can reach out to your study contact person shown on the back of your painTRAINER® Workbook.

- **What information does painTRAINER® collect about me? And what will you do with this information?**

Answer: The program will ask you for your email address so it can send you reminders to complete sessions or practice skills. It will also track when you sign into and out of the program, which parts of the program you visit or use, and your responses to questions and exercises. It is important for you to know that this information is stored on a secure computer drive and only certain people in the study can access it. The information will help us understand how people use the program so that the study can learn whether that is related to the benefits people get out of using it. The information also helps us improve the program. We will not connect your name with the information the program collects. It does not track anything outside of the painTRAINER® program (for instance, it will not collect data on what websites you're using).

Note: For questions related to technical problems with the painTRAINER® program (including problems getting to the website, registering, signing into the program, or using it), see the *painTRAINER® Technical Support Procedures section* below.

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c. Technical Support Procedures

Part 1: Technical Questions Participants May Have

Below we have tried to describe the most common technical problems that participants may experience. This information is also contained in the painTRAINER® participant guide, so your participant may have tried all of these solutions before contacting you and may be frustrated. If you cannot resolve a problem quickly using one of the methods suggested below, we can work with the participant to troubleshoot and solve the problem (see Part 3).

- **Issue: *I'm having problems registering to use painTRAINER®. How can I get registered so I can start using the program?***

Problems with registration may happen if a participant has a device, operating system, or web browser that is not supported by the program. You can read about supported devices, operating systems, and web browsers in Part 2 of this section.

The painTRAINER® Startup Guide within the painTRAINER® Participant Guide has step-by-step registration instructions and describes some problems participants may have when they are registering. If you are contacted by a participant who is having problems registering, try following the instructions in that guide. Some common problems may include:

- ***Having problems entering their email address.*** Participants will be asked to enter their email address and then enter it again to confirm it. If they do not enter their email address exactly the same way in the two boxes, the program will let them know and they should try entering their email address again, being sure to enter it exactly the same way in the two boxes.
- ***Having problems entering their password.*** Participants will be asked to enter their password once and then enter it again to confirm it. This is standard practice on many websites, so hopefully it will not be unfamiliar to most people. **Passwords must be at least 8 characters long and they must contain at least one capital letter, at least one number, and at least one special character (for instance: @ # % \$ *).** If they do not enter their password exactly the same way in the two boxes, the program will let them know: the box around the confirmed password will turn red and a box will appear that says “the passwords entered do not match.” and they should try entering it again, being sure to enter it exactly the same way in the two boxes.
- ***Forgetting to check the box next to “Terms of use.”*** This box allows participants to read the painTRAINER® *Terms of Use and Privacy Policy*. They need to select the box and accept the terms before they can select the REGISTER button.

Participants who do not want to accept the terms will select “I do not accept”; they will not be able to complete registration or use painTRAINER®.

The *painTRAINER® Frequently Asked Questions and Responses* section of this document can help you answer any questions participants may ask about the information that painTRAINER® collects.

- **Issue: *I'm having problems logging into the program. Can you help?***

For this kind of problem, refer to the **painTRAINER® Start Up Guide** within the painTRAINER® Participant Guide. It has very detailed instructions for logging into the program. It also describes some mistakes that could make it hard for participants to log in. These problems include:

- ***Going to “paintrainer.org” instead of “mypaintrainer.org”*** (e.g., participants who do this won't see a pull-down mention to select their study, in addition to other problems. See issue #4, below, to get more help figuring out if the participant may be on the wrong website).
- ***Not knowing their Username.*** Let the participant know that their username should be written on the back of their painTRAINER® workbook. In IMPACTS, the participant's username is their participant ID (PID) number. To recover a lost userid, have them go to *mypaintrainer.org*, select “LOGIN” in the upper right-hand corner of the screen, then select “Lost Login Details” on the bottom of the window that pops up (see below). On the next window, they'll select “Forgotten Username” and follow instructions for recovering it. Once they have recovered their username, ask them to write it on the back of their painTRAINER® workbook or in another convenient place.

The screenshot shows the LOGIN page with fields for Username and Password. A checkbox for "Remember me" is checked. At the bottom, there are links for "Register" and "Lost Login Details" (circled in red), and a "LOGIN" button.

The screenshot shows the LOST LOGIN DETAILS page with two tabs: "Forgotten Password" and "Forgotten Username" (circled in red). Below the tabs is a field for "Enter your Email address" and a "SUBMIT" button.

- ***Forgetting their password.*** Have the participant go to *mypaintrainer.org*, select “LOGIN” in the upper right hand corner of the screen, then select “Lost Login Details” on the bottom of the window that pops up (see below). On the next window, they'll select “Forgotten Password” and follow instructions for recovering it.

The screenshot shows the LOGIN page with fields for Username and Password. A checkbox for "Remember me" is checked. At the bottom, there are links for "Register" and "Lost Login Details" (circled in red), and a "LOGIN" button.

The screenshot shows the LOST LOGIN DETAILS page with two tabs: "Forgotten Password" (circled in red) and "Forgotten Username". Below the tabs is a field for "Enter your Username or Email address" and a "SUBMIT" button.

- **Issue: *What should I do if painTRAINER® screens are not working correctly on my device?***

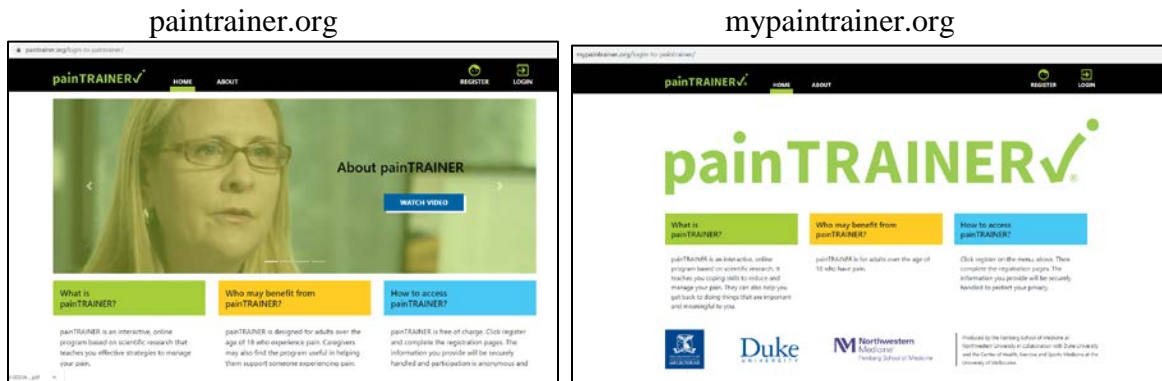
If a participant cannot hear the audio in painTRAINER®, ask them to check the volume on their device to make sure it is not muted or turned down very low.

If the problem is not with the audio, read Part 2 to make sure the participant is using a supported device, operating system, and web browser.

- **Issue: When I try to register for painTRAINER® I don't see a place to select my Study Code. How do I handle that?**

Your participant may have gone to the “paintrainer.org” website instead of the “mypaintrainer.org” website. For this study, be sure your participants use the mypaintrainer.org website. The paintrainer.org website takes them to an Australian version of painTRAINER®. It's very similar to the version they will use on mypaintrainer.org, but it was not designed for use in a research study and it has not gone through the same extensive testing.

If they have entered paintrainer.org (the wrong website), they will see a photo of a blond woman (Dr. Kim Bennell) on the webpage (see photo on the left, below). The correct website (mypaintrainer.org) does not have the photo of Dr. Bennell.



- **Issue: What should I do if I enter mypaintrainer.org into my web browser but it doesn't take me to the painTRAINER® program?**

First, double-check that they have entered the correct address. Even a slight error can result in being taken to the wrong place.

If your participant is repeatedly taken to the wrong website when entering mypaintrainer.org, they may have malicious software (“malware”) on their device that is re-directing them to another website. A quick fix is that you can email them a link to the mypaintrainer.org website. That should allow them to access it. In addition, if they have an antivirus program on their device, ask them to try running it to find and remove malware. They may need to call a help line or talk with an expert to get the malware off their device. They may feel frustrated by the need to do that, but emphasize that it will be important to get it off their device for other reasons, not just for the study.

If they have a different device they can use to access painTRAINER®, they may be able to get started on the program using that device as they resolve any issues with malware.

If it appears that there could be a technical problem that can't be readily solved or if appears that there may be a technical glitch in painTRAINER® that has not been found or fixed, please refer to Section 3, below.

Part 2: Supported Devices, Operating Systems, and Web Browsers

Devices and Operating Systems

Here are some devices participants can use to access the painTRAINER® program:

- **Smartphones** – For example, an Apple iPhone, Samsung Galaxy, or Google Pixel, but there are other types of smartphones you can use. They just have to be able to access the Internet. Smartphones usually run on the iOS (Apple), Android, or Windows operating system. Trying to use a smartphone that is more than a few years old could cause problems with how painTRAINER® runs.
- **Tablet computers** – For example, an Apple iPad, Amazon Fire, Samsung Galaxy Tab, Lenovo Yoga, or Microsoft Surface, but there are other types of tablet computers your participants can use. Tablet computers usually run on the iOS (Apple), Android, or Windows operating system. Using a tablet computer that is more than a few years old could cause problems with how painTRAINER® runs.
- **Laptop or desktop computers** – For example, a personal computer that runs on the Windows operating system (PC) or an Apple Macintosh (Mac) computer. If your participant will use painTRAINER® on a PC or Mac, it is best if its operating system is not too old.

For Macs, the most recent operating system (as of July, 2020) is macOS 10.15 Catalina (Jazz). For PCs (Windows computers), try to make sure your participant is using Windows 10, but Windows 8 or 8.1 may also work.

If your participant is using a macOS or Windows operating system that is older than those described above, that may be a reason they are having problems with painTRAINER®. Updating the operating system is fairly involved and is likely to involve some expense. It may be best to ask them to try a different device if they have access to one, such as a tablet computer or a smartphone. You can also request a tablet in the WF1901-IMPACTS-Tablet Lending project through REDCap.

One reason to consider updating an operating system is that the newer versions should have better security protections. If your participant requires support to upgrade his or her operating system, please contact the IMPACTS study team at ncorp@wakehealth.edu to make arrangements for someone to contact the participant and provide technical support to do this.

Recommended web browsers

All of the devices listed above use web browsers to access websites such as *mypaintrainer.org*. For the easiest and most secure use of painTRAINER®, it is best if participants use one of these web browsers:

- Google Chrome version 75 or newer on Windows laptops/desktops, Mac laptops/desktops, or Android phone/tablet.
- Microsoft Edge version 80 or newer on Windows or Mac laptops/desktops.
- Safari version 12 or newer on Mac laptops/desktops or iPhone/iPad.

If participants are unable to use one of the web browsers listed above, they can use one of the following web browsers:

- Firefox version 68 or newer on Windows, Mac, or Linux laptops/desktops.
- Internet Explorer version 11 on Windows 10 laptops/desktops.

The painTRAINER® Registration and Login pages contain the most up-to-date information about supported web browsers. If your participant requires support to upgrade his or her web browser or to download a new web browser, please contact the IMPACTS study team at ncorp@wakehealth.edu to make arrangements for someone to contact the participant and provide technical support to do this.

Part 3: Escalating More Complex Technical Problems

If you cannot resolve a problem quickly using one of the methods suggested above, we can work with the participant to troubleshoot and solve the problem so they can get back on track in the study. To escalate a problem so that this troubleshooting can occur, please take the following steps:

1. Send an email to NCORP@wakehealth.edu.
2. In the subject line, write “WF-1901: URGENT PARTICIPANT TECHNICAL PROBLEM”.
3. In the body of the email, provide the participant’s PID preferred days/times of contact, if you know of any.
4. Provide the following information:
 1. A description of the problem.
 2. Any information on what you have tried to do to resolve it.
 3. The type of device they are using, the operating system on their device, and the web browser they are using (if known).

Please follow your institution’s guidelines for making this email secure. At some institutions, this may include “Secure:” or [secure] in the subject line of your email. In Outlook, you may be able to click on “Options” or similar menu item near the top of the email you are composing, then look for a menu item that allows you to encrypt the message.

painTRAINER® Group v07.28.2020-R

VIII. Helpful Eligibility Tips

a. Determining Eligibility for IMPACTS

Short-term or acute pain syndromes last less than 3 months and may occur after cancer-related diagnostic, therapeutic, and analgesic procedures as well as various cancer therapies, or due to neoplasm, infection, or related pathology. Patients experiencing only acute pain are not eligible for the IMPACTS study since eligible patients have ongoing chronic pain.

To be eligible for the IMPACTS study, patients must report chronic pain (pain lasting 3 or more months) that is either NEW (since the development of cancer or cancer treatment) or EXACERBATED (pain that was made worse since the development of cancer or cancer treatment). Patients may be off all treatment or actively receiving treatment for cancer that is felt to be stable and/or controlled per clinician judgement.

In addition to experiencing chronic pain, the patient must report pain that is a score of 4 or greater on the Pain Intensity Scale, and must report experiencing pain on MOST days of the week (4 or more days).

Patients with chronic pain syndromes that are common among cancer survivors following their diagnosis and/or treatment are:

- Tumor-related Nociceptive Pain Syndromes
 - Bone and joint/soft tissue pain syndromes (e.g., arthritis, autoimmune disorders)
 - Paraneoplastic pain syndromes
 - Neoplastic involvement of viscera
- Tumor-related Neuropathic Pain Syndromes
 - Peripheral mononeuropathies
 - Polyneuropathies
 - Plexopathy
- Treatment-related Nociceptive Pain Syndromes
 - Osteonecrosis
 - Lymphedema
 - Gynecomastia
 - Chronic abdominal pain
 - Radiation-induced chronic pelvic pain
- Treatment-related Neuropathic Pain Syndromes
 - Post-surgical neuropathic pain syndromes
 - Post-radiotherapy pain syndromes
 - Post-chemotherapy pain syndromes

(continued on next page)

Additional chronic pain syndromes associated with cancer treatment are listed in the table below:

| Table 3. Chronic Pain Syndromes Associated With Cancer Treatment |
|--|
| <p>Chemotherapy-related pain syndromes</p> <ul style="list-style-type: none"> Bony complications of long-term corticosteroids Avascular necrosis <ul style="list-style-type: none"> Vertebral compression fractures Carpal tunnel syndrome Chemotherapy-induced peripheral neuropathy Raynaud’s syndrome |
| <p>Hormonal therapy-related pain syndromes</p> <ul style="list-style-type: none"> Arthralgias Dyspareunia Gynecomastia Myalgias Osteoporotic compression fractures |
| <p>Radiation-related pain syndromes</p> <ul style="list-style-type: none"> Chest wall syndrome Cystitis Enteritis and proctitis Fistula formation Lymphedema Myelopathy Osteoporosis Osteoradionecrosis and fractures Painful secondary malignancies Peripheral mononeuropathies Plexopathies: brachial, sacral |
| <p>Stem-cell transplantation-mediated graft-versus-host disease</p> <ul style="list-style-type: none"> Arthralgias/myalgias Dyspareunia, vaginal pain Dysuria Eye pain Oral pain and reduced jaw motion Paresthesias Scleroderma-like skin changes |
| <p>Surgical pain syndromes</p> <ul style="list-style-type: none"> Lymphedema Postamputation phantom pain Postmastectomy pain Postradical neck dissection pain Postsurgery pelvic floor pain Post-thoractomy pain/frozen shoulder Postsurgery extremity pain (eg, sarcoma) |

Source: Paice JA, et al. (2016). J Clin Onc 34:3325-3345.

Patients with pain syndromes un-related to cancer may also be eligible if their pain is new or exacerbated since cancer diagnosis or treatment.

b. Identifying Eligible Patients

To identify potentially eligible participants to contact, you can screen previous clinic notes and/or search the electronic medical record (EMR) for “clues”:

Note: potential patients must meet all other criteria, see full protocol for details.

- Look for one of the pain diagnoses/syndromes listed above in the electronic or written problem list.
- Search the medication list for narcotics or adjuvant analgesics like gabapentin or pregabalin.
- Identify pain scores (often collected with vital signs) for patients who report moderate or higher pain at the time of their last clinic visit.
- Identify patients through chart documentation (clinic notes, telephone notes) who have recently had their analgesic doses modified or who have been referred to a pain management consultant or palliative care consultant for advice on pain management

Potentially eligible participants may also choose to inquire about the study or choose to self-enroll based on IRB approved study advertisements.

- Place IRB approved study advertising flyers in waiting areas or exam rooms for patients to self-refer based on their ongoing pain issues. Recruitment flyers and posters can be downloaded from CTSU protocol documents section.

c. Eligibility / Enrollment FAQ

- We are not limiting eligibility to either nociceptive pain or neuropathic pain. As long as the pain is due to cancer or cancer treatment and the candidate meets the other criteria, they are eligible.
- MDs and advanced practitioners who are registered in RCR as IVR or NP/IVR can enroll patients in this study.
- An analgesic is anything that is used to relieve pain. NSAIDs are also a common treatment. Patient does not have to be on an opiate regimen to be eligible. Patient can also be on **no analgesic** and still be eligible.
- Cannabis is an acceptable analgesic if used medicinally and must be documented along with other medications on the “*7 Day Medication Dairy & Typical Usage*” form.

IX. Other IMPACTS Study FAQ

Gift Card Distribution & Questions

- Gift cards will be distributed by the WF NCORP RB directly to the participants. The WF-1901 funding sheet has the gift card amounts. Distribution of the gift cards for completion of interviews and questionnaires will be shortly after completion directly to the participant. Distribution of the gift card for the completion of the Medication Diaries will be the cumulative amount over the study. It will be provided once the participant completes the study or at the time of early termination. Any questions should be emailed by the local NCORP site to NCORP@wakehealth.edu.