

DAISY Finger Poke Protocol

Aim: To offer families DAISY Autoantibody testing in 2020.

Method: Parents/Child will be offered the opportunity to review a video <https://youtu.be/idOMCtBfLLs> to determine if PARTICIPANT or BOTH PARTICIPANT and PARENT find it feasible to collect blood via a capillary sample to test for autoantibodies. Clinical measurements (height and weight) will also be obtained by parent when possible.

Eligibility: All AB-Negative subjects are overdue or due for a clinic visit. In addition, any AB+ participant or parent not willing to come to the BDC for an in-person visit.

Subject Payment: All subjects will received \$20 for the blood sample. **The W9 will be required for subject payment.**

Human Subjects: The home capillary protocol and video are a DAISY COMIRB approved protocol. No further consent needed other than verbal/emailed agreement to complete the protocol. However, if the participant is 10 years old, a child assent should be mailed. If the participant is 13 years old, the consent should be mailed. If the participant is 18 years old, a consent should be mailed for the participant to sign themselves.

DAISY Procedure:

- DAISY Annual Update Interview will be collected over a phone interview before the finger poke visit.
- Participants are asked to contact DAISY with the date of the finger poke. The participant will be added to the scheduling system in order for the visit to be entered and updated as COMPLETED once the kit is returned.
- The DAISY clinic visit data entry will need to be completed once kit is returned and processed. Clinical measurements collection date and by parent, date/time of blood collection and shipping date should be documented. The DAISY Finger Poke Specimen form will have the date and time of the blood collection.

Finger Poke Kit:

1 chux
 2 yellow top micro-containers
1 purple top micro-container (if AB+)
 1 ETOH pad
 2 Gauze/cotton balls
 2 band aids
 2 blue lancets
 1 hot pack

FEDEX Pack

1 padded envelope (accelerometer size; in lab bottom shelf)

1 return DAISY sender/ DAISY receiver FEDEX label generated by FEDEX

1 envelope containing:

- Diet survey and FFQ
- Finger Poke Specimen Collection Sheet
- W9 (if participant/family has not previously received check payment)
- Consent (if turned 18 yrs old since last consent signed)

**Email DAISY FPP Elig for availability in next 1-2 weeks
REPLY**

AGREED



FEDEX Kit Prep:

- 1) FPP kit with specimen collection form
- 2) Consent
- 3) W9
- 4) Diet forms
- 5) FEDEX return label
- 6) FEDEX Express Clinical Pak



Email FEDEX is on the way w/in 3 days of sent

- 1) Schedule date (not time) in DAISY local as an **LDP participant**
- 2) Schedule if Zoom Clinic Support req

DECLINE



- 1) Confirm interview is complete
- 2) Notify Iman of Subject ID number-she will update next due date

1st EMAIL: Email for FPP Elig (completed Annual Update Interview)/Available in the next 2 weeks

Dear DAISY Participant,

Thank you again for taking the time to complete the phone interview with us. As per our conversation, the DAISY study may not be able to do in person visits to collect the blood sample in the near future as the University is moving very carefully about reopening research. We have developed a finger poke protocol for families to collect a small blood sample at home and send it in for antibody testing. You would receive results from this testing as you normally do.

Below is a link of a video link to explain what is needed to complete the blood collection at home (PLEASE view the video as soon as possible to determine if that is something you will be interested in doing)

<https://youtu.be/idOMCtBfLls>

Please respond to this email with AGREED or DECLINE in the subject line. Also, let us know if you have had a change in address in the last 3-6 months.

Please remember, this is voluntary. If you AND/OR your child agree, supplies will be sent out within the week. If do not think this is something you can do at home, that is okay too.

The DAISY participant will receive their \$20 for completing the DAISY Finger Poke. A check will be processed and mailed to your home.

Thank you for your consideration!

DAISY Study Staff

**DAISY Finger poke kit is on the way! Email
Send 1-3 days after FEDEX is sent**

Dear DAISY Participant,

Thank you for your willingness to complete the DAISY Finger Poke protocol from home. Your kit is on the way. It should arrive within the next few days.

Please plan on completing the finger poke within a week of the kit arriving at your home. We appreciate you letting us know the day you plan to complete the kit so the lab knows when to expect the kit.

If you would like additional clinic support via Zoom to assist you with the finger poke, let us know. A clinician will set this up and email you an invite.

Here are a couple of tips we hope you will find useful in having success at home:

1. Please plan on completing the finger poke on a **Mon-Wed** and sending the FEDEX the **same day as the finger poke.**
2. The blood should stay at room temperature.
3. Please include the date and time of the fingerpoke and return all paperwork in the kit.
 - If participant has reached 18 yrs of age since last consent was signed, a new **consent** is included and should be signed by the participant.
 - Complete the **Diet Survey** (yellow) and the **Food Frequency Questionnaire**.
 - Fill out the **W9** with information for whomever you would like check to be made out to: name, address, SSN and sign and date.
4. **We really need to have at least 1 of the microtainers filled between 400-600 to do the autoantibody testing.**

FOR A SUCCESSFUL FINGERPOKE:

- Please make sure the fingers are warm. If the hot pack is not enough, rubbing the fingers together, putting the fingers in very warm water or washing hands with warm water are additional ideas.
- Please make sure you press the lancet very firmly on the finger when you complete the poke to ensure good blood flow.

<https://youtu.be/idOMCtBfLls>

If you have any additional questions, please respond to this email or call the [DAISY line at 303-724-7622](tel:303-724-7622).

Thank you for your dedication to the DAISY Study!

The DAISY Study Staff

Reminder text/email if FEDEX is not returned within 1 week of sent

Dear DAISY Family,

We want to confirm your DAISY Fingerpoke kit has arrived. It was sent out on XX-date.

Please complete the W9 form and return (name, address, SSN, and sign/date)

Please complete the diet survey and FFQ and include the date completed

Please sign and return the consent (if included)

Please complete and return the specimen collection form

Return all paperwork in the enclosed envelope

Please respond to this text if you would like additional clinic support via Zoom to assist you with the finger poke. A clinician will set this up and email you an invite.

Helpful tips for the DAISY Finger Poke have been sent to your email.

We appreciate a response to this message on the day you plan to complete the finger poke so we know when to expect your sample. You can also call our direct line at 303-724-7622 if you have any immediate questions or concerns.

Thank you,

DAISY Study Staff

Email/Text reminder if still have not returned kit after 3 weeks from send date:

Dear DAISY participant,

We thank you for your participation in DAISY and for completing the annual interview questionnaire over the phone. We have not received the finger poke kit please let us know when you are planning to mail it back by replying to this email/text. The blood sample is very important for checking your autoantibody status for type 1 diabetes. You will be compensated \$20 for your DAISY visit when we receive your blood sample.

If we don't hear back from you or receive the kit by the end of the week of (enter following week's date), we will close out your visit for this year and attempt to obtain a blood sample next year.

We realize it's a challenging time and we truly appreciate your participation in DAISY. As always, feel free to reach out to us if you have any questions or concerns at 303-724-7266.

We look forward to hearing back from you and receiving your samples.

Thank you,

Daisy Study Staff

TEDDY FEDEX SHIPMENT

2 FED EX Labels will be generated per kit: # 1 TO: DAISY Participant/ FROM:DAISY and #2 FROM: DAISY Participant/ TO: DAISY

1) Go to FEDEX.com

LOGIN

- USER ID: teddystudy
- PASSWORD: Teddyfedex1212
-

2) GO TO SHIPPING

CREATE A SHIPMENT

1. From

Kathleen Waugh, 1775 Aurora Court F527, Rm 2213, Aurora, Colorado, 80045, United States

2. To

- Enter DAISY participant, ADDRESS, CITY, STATE, ZIP and PHONE # (should have been confirmed when interview completed)

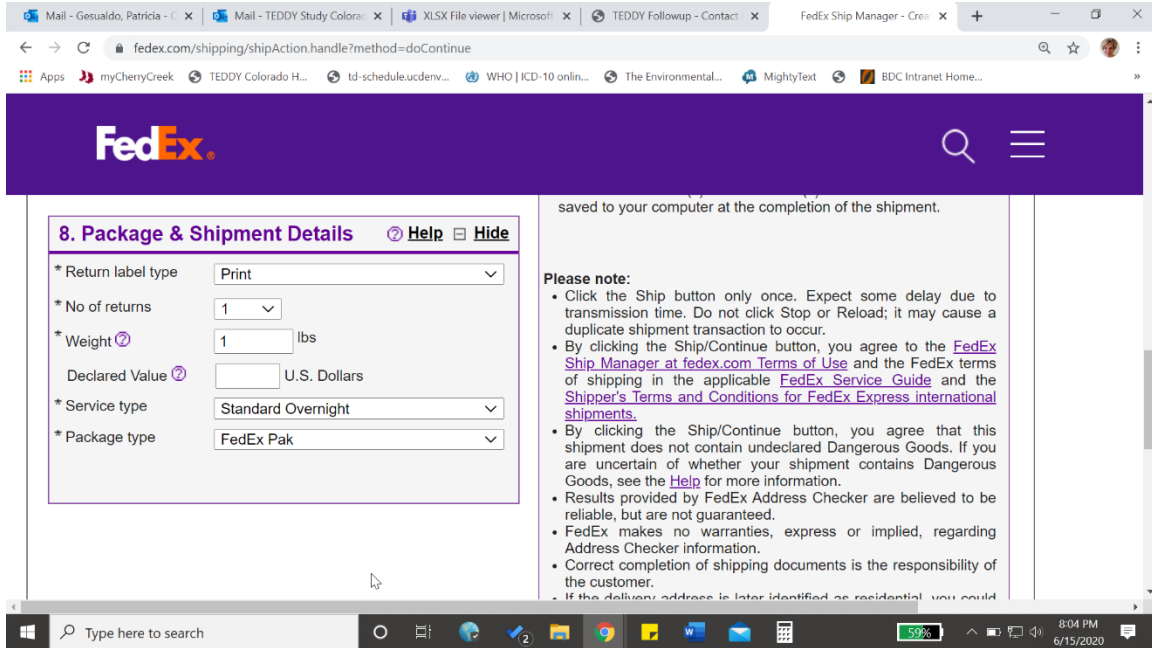
3. Package & Shipment Details

- Select FEDEX EXPRESS SAVER (unless time sensitive)
- Package Type: FEDEX PACK
- No. of Packages: 1
- Weight 1 lbs
- Dimensions: FEDEX Pak
- Select INCLUDE A RETURN LABEL

4. Billing Details

- Your reference: DAISY speedtype 63012454

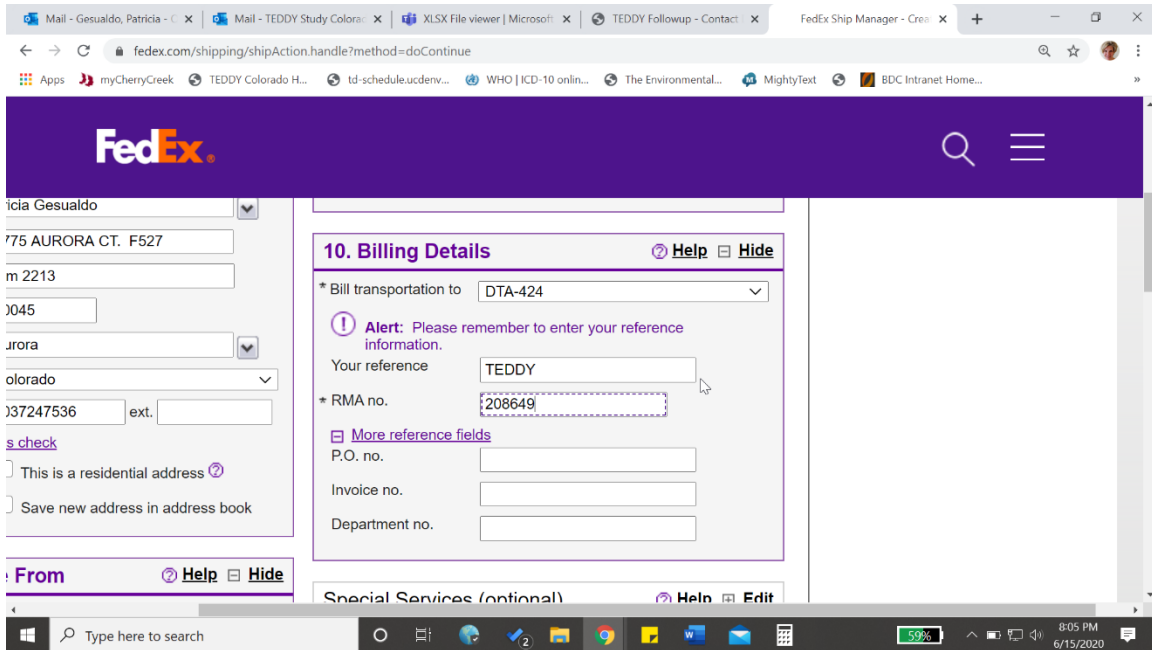
5. SELECT Continue to Return Shipment**Section 8. Package & Shipment Details**



Section 10. BILLING DETAILS

Reference: DAISY

RMA No: Subject ID



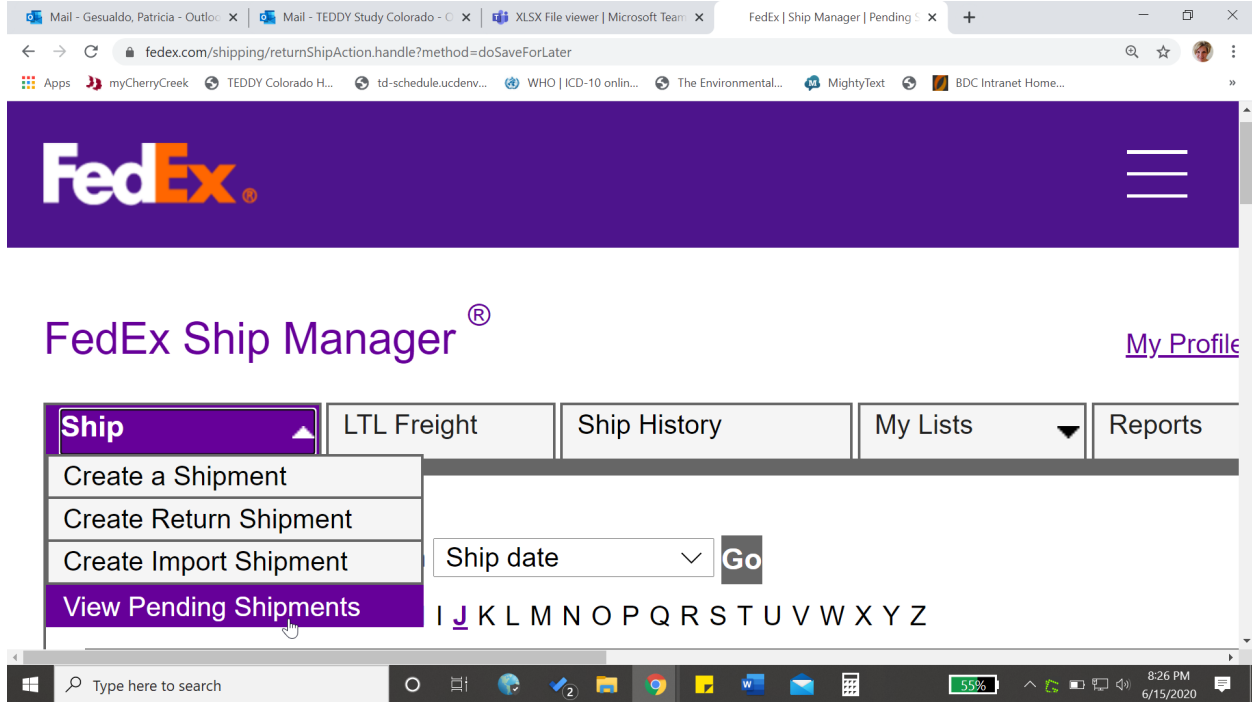
IF SENDING INDIVIDUAL LABELS:

SELECT PRINT

IF BATCHING a SERIES OF LABELS:

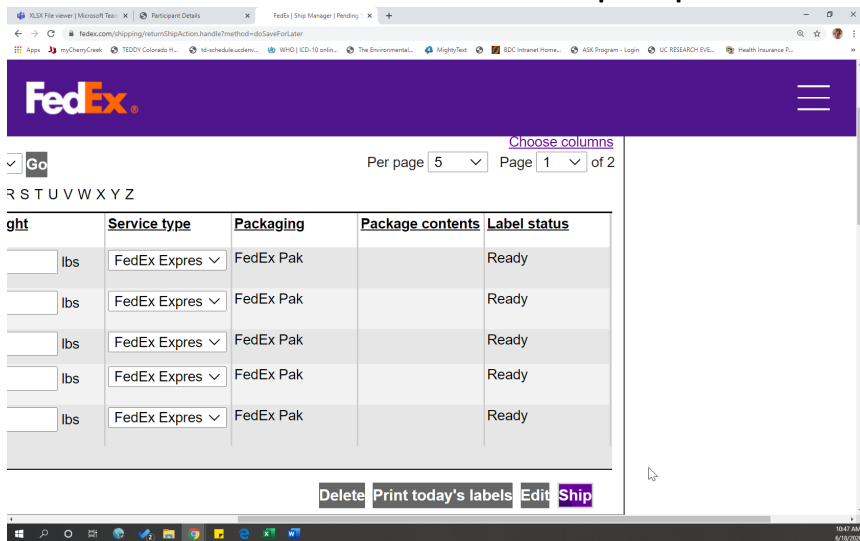
Select **SAVE FOR LATER**

List can be located in **PENDING SHIPMENTS** in the **FEDEX SHIP MGR**



SELECT PRINT TODAY'S LABELS.

Check to make sure Label Status is **READY** for all participants

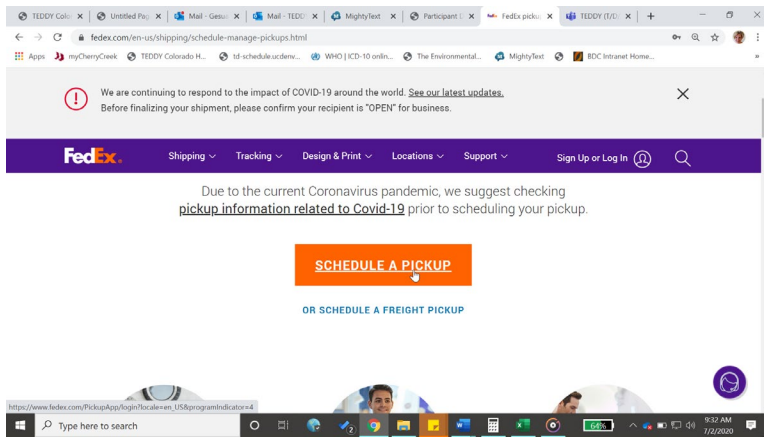
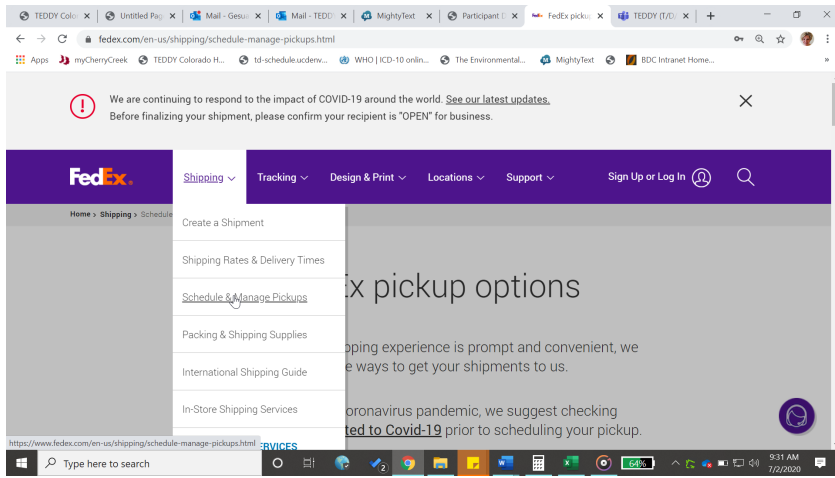


How to Schedule a FEDEX PickUp

Login:teddystudy

Password: Teddyfedex1212

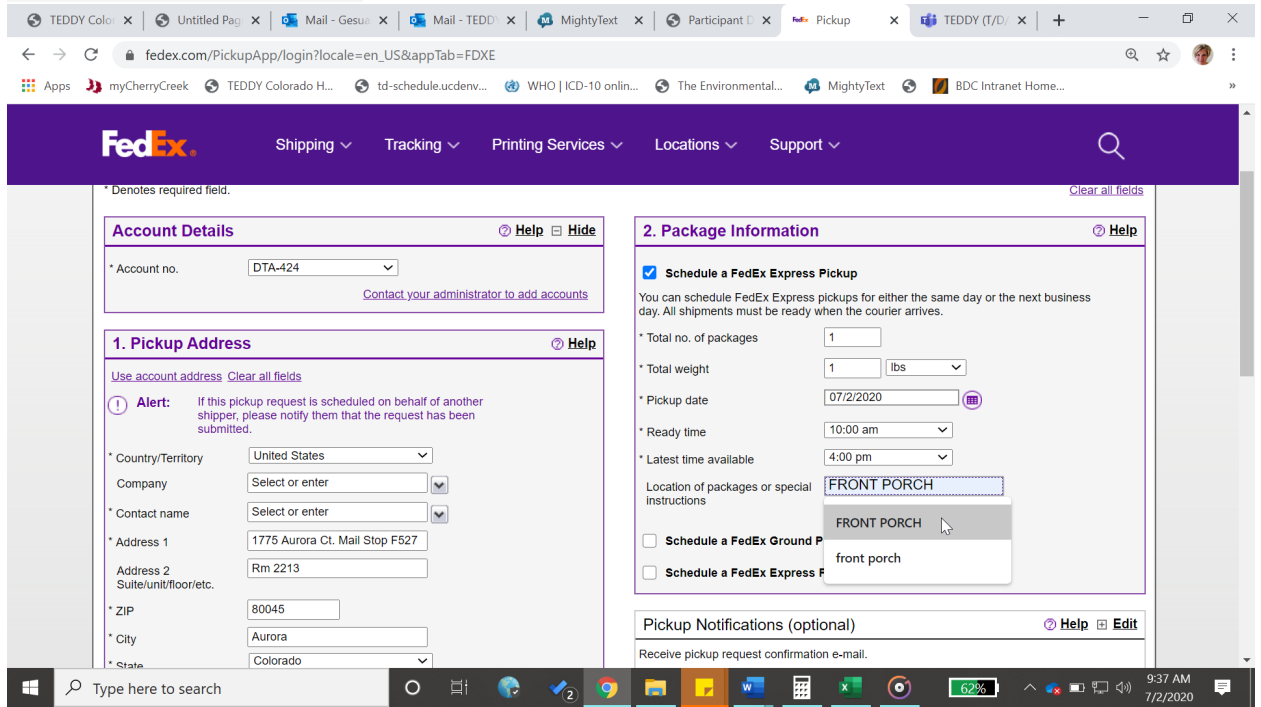
Go to Shipping and select Schedule and Manage Pickups



1. **Pick Up Address:** Enter Parent name, address and phone # of participant. Select This is a Residence
2. **Package Information:** Schedule a FEDEX Express PickUp

You can schedule FedEx Express pickups for either the same day or the next business day. All shipments must be ready when the courier arrives.

Select a 4 hour window with parent
Include location of package



3. **Complete Pickup:** Select Schedule Pickup
Email parent the confirmation

DAISY LAB:

A whole blood sample will be taken by subjects per home finger poke protocol.

- Obtain 1-2 SST bullets of whole blood via finger poke and one small EDTA pink top (if DM AB+)
- Run A1c, RG and HemoCue (if needed) from purple top microtainer
- Centrifuge SST bullet(s) for 10 min at 1500g (program 1)
 - i. If total serum sample from SST bullets is less than 100 μ L notify Kathy Waugh immediately via email
- Print/copy blank DAISY clinic visit sheet
- Assign LABID to subject visit-sticker on 1.0ml cryovial, clinic visit sheet, antibody send tracking form
- Make aliquots of serum:
 - i. Aliquot **.25mL** into a 1.0mL cryovial with assigned LABID sticker for antibody testing (to be sent upstairs)
 - ii. Aliquot **.2mL** into a 0.5mL labeled cryovial for QC, additional QC (0.1, 0.2ml) samples if any serum is remaining
 1. Save in the QC box

DAISY LAB DATA ENTRY:

Update the LD/FFQ Outcome Data Entry for the outstanding kit and FFQ

Go to the Clinic Visit tab and add a New Clinic Visit

Enter the date of blood sample collection as the Date of Visit

Enter the blood volume and height and weight if provided

Complete Draw Site Detail: Fingerpoke

Indicate "COVID-19 Finger Poke" in the Clinic Comments field

Complete the Clinic Visit data entry

Put completed W9 Forms in Kathy Waugh's mailbox or office

Put completed diet forms in the basket in the records room

Please email Kathy Waugh with any deviations to the protocol

EX: If the fingerpoke sample results in the antibody serum sample <100ul OR if the participant should have a purple top bullet for HbA1c analysis but this sample is not included in the returned samples.