rFVIIa for Acute Hemorrhagic Stroke Administered at Earliest Time (FASTEST) Trial

Noor Sabagha RPH, MPH
NIH StrokeNet Clinical Research Pharmacist
16Sep2021 v1.0

Prior to Readiness call

Complete site Pharmacy regulatory

Receive study drugs

Readiness call

(Ask questions!)

Site Pharmacy Regulatory in WebDCU™

- ❑ Institutional pharmacy license and Drug Destruction Policy must be uploaded into WebDCU™
  WebDCU™> Regulatory Documents> Site Reg Doc Submission

- ❑ Institutional pharmacy license address and drug shipping address must match.
  If the addresses do not match, please notify the *or the StrokeNet NCC Central Pharmacy @ (FASTESTtrialrx@ucmail.uc.edu)*

- ❑ The DOA includes at least one person with pharmacy privileges

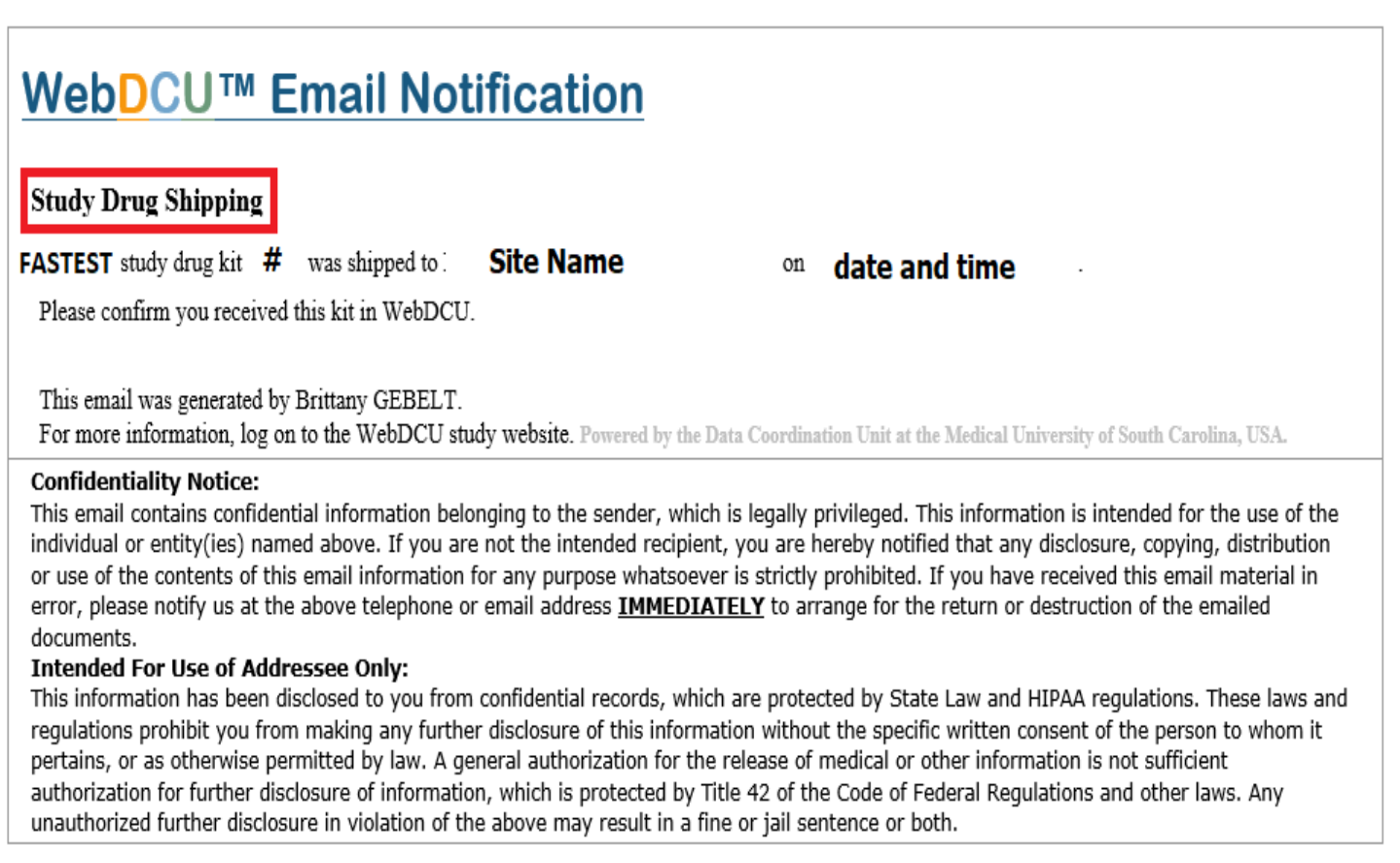
****Please note that site pharmacy personnel do not have privileges to upload those documents.**

- ❑ When a Clinical Performing Site (CPS) is released to receive study drug, an initial study drug shipment will automatically be submitted to NCC Central Pharmacy by WebDCU™

- ❑ Central research pharmacy at UC ships study medication few days prior to readiness call.

- ❑ NCC Central Pharmacy will ship study drug kits Monday through Wednesday for next day delivery Tuesday through Thursday. No shipments will take place for receipt on Friday, Saturday, Sunday, or holidays, except under extenuating circumstances

WebDCU™ Study Drug Shipping Email



WebDCU™ Email Notification

Study Drug Shipping

FASTEST study drug kit **#** was shipped to: **Site Name** on **date and time** .

Please confirm you received this kit in WebDCU.

This email was generated by Brittany GEBELT.
For more information, log on to the WebDCU study website. Powered by the Data Coordination Unit at the Medical University of South Carolina, USA.

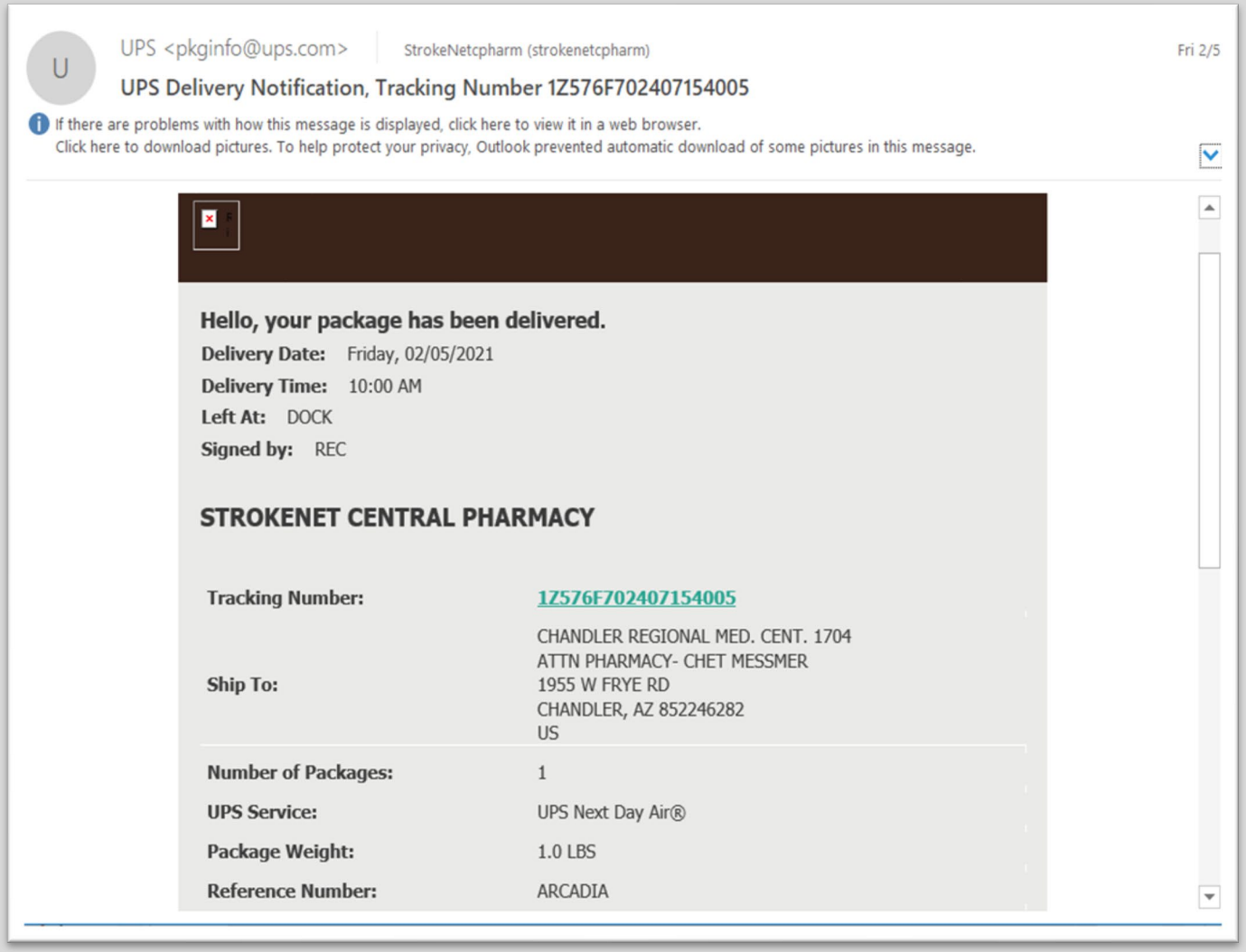
Confidentiality Notice:
This email contains confidential information belonging to the sender, which is legally privileged. This information is intended for the use of the individual or entity(ies) named above. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or use of the contents of this email information for any purpose whatsoever is strictly prohibited. If you have received this email material in error, please notify us at the above telephone or email address **IMMEDIATELY** to arrange for the return or destruction of the emailed documents.

Intended For Use of Addressee Only:
This information has been disclosed to you from confidential records, which are protected by State Law and HIPAA regulations. These laws and regulations prohibit you from making any further disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. A general authorization for the release of medical or other information is not sufficient authorization for further disclosure of information, which is protected by Title 42 of the Code of Federal Regulations and other laws. Any unauthorized further disclosure in violation of the above may result in a fine or jail sentence or both.

- CPSs will receive an automated email from WebDCU™ for every study drug kit that was processed out of WebDCU™ for shipment.
- For example, if a shipment has 4 study drug kits in the shipment, the CPS will receive an individual email for each kit (4 emails).

FASTEST

UPS® Shipping Notification Email



- CPSs will also receive an email from UPS® that includes a tracking number and any updates to shipment during transit for every shipment
- CPSs may request a group pharmacy email to receive UPS® tracking information by emailing the StrokeNet NCC Central Pharmacy (*FASTESTTrialRX@uc.edu*) the group pharmacy email address
- UPS® tracking website: https://www.ups.com/WebTracking/track?loc=en_US

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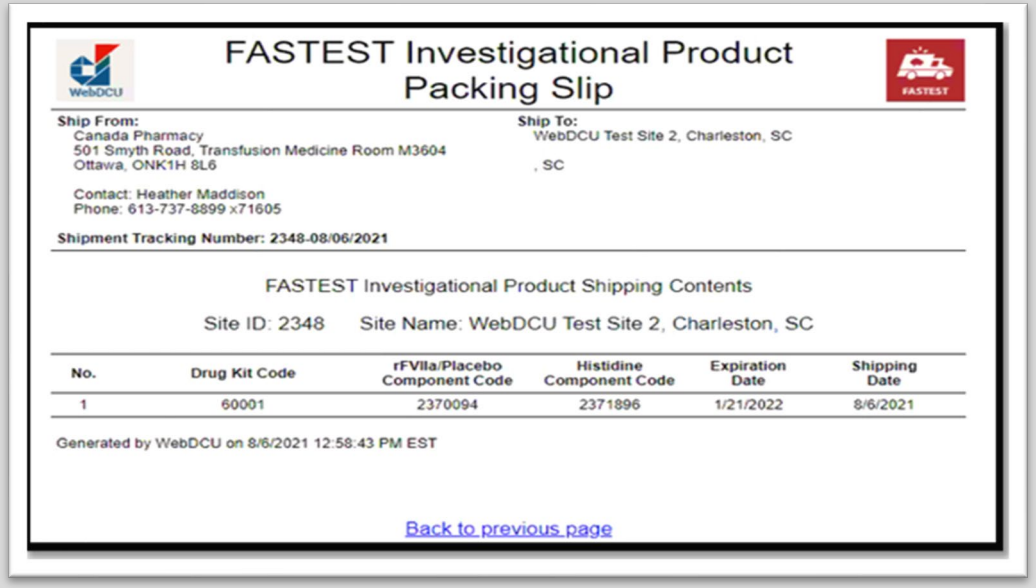
Study Drug Packaging and Packing Slip

Study drugs will be shipped refrigerated

Study drug will be shipped with a USB temperature logger, cold packs, and enough insulation to maintain a temperature range of 2-25°C (36- 77°F)

Insulated Shipping Container

Temp-Tale



FASTEST Investigational Product Packing Slip

Ship From:
Canada Pharmacy
501 Smyth Road, Transfusion Medicine Room M3604
Ottawa, ONK1H 8L6

Contact: Heather Maddison
Phone: 613-737-8899 x71605

Ship To:
WebDCU Test Site 2, Charleston, SC
, SC

Shipment Tracking Number: 2348-08/06/2021

FASTEST Investigational Product Shipping Contents

Site ID: 2348 Site Name: WebDCU Test Site 2, Charleston, SC

No.	Drug Kit Code	rFVIIa/Placebo Component Code	Histidine Component Code	Expiration Date	Shipping Date
1	60001	2370094	2371896	1/21/2022	8/6/2021

Generated by WebDCU on 8/6/2021 12:58:43 PM EST

Back to previous page

Packing Slip

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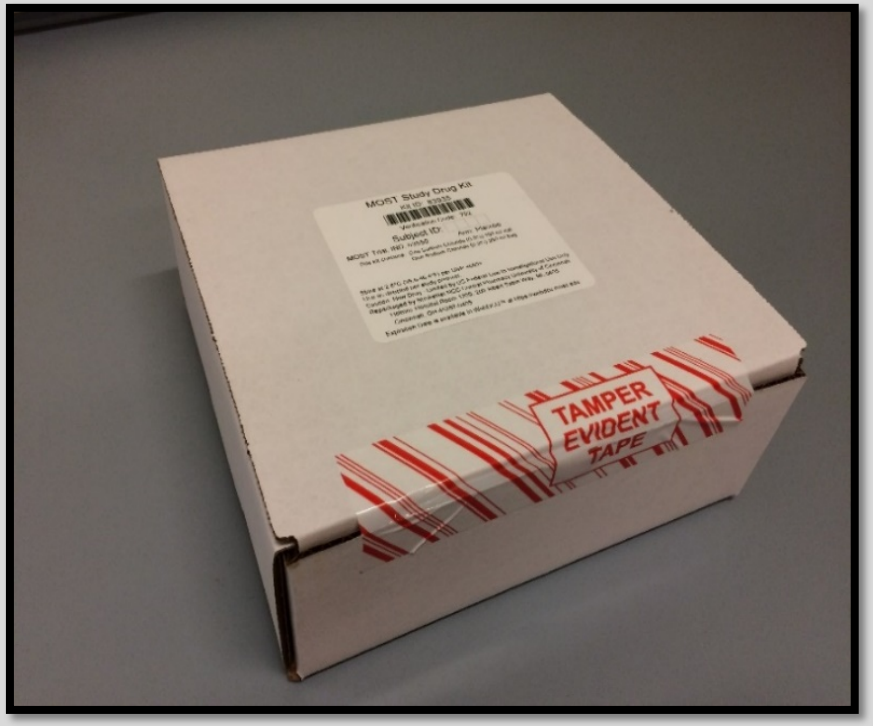
Example Kit Label

FASTEST
Study Drug Kit ID: 32565
621

Identité de la trousse du médicament à l'étude
Studienmedikations-Kit ID
ID del kit de medicamentos del estudio
試験薬キットID

Verification code

Study Drug Kit Box



FASTEST **IND #18150**

Study Drug Kit ID: 32565
621

This kit contains
Two recombinant Factor VIIa 5mg or Placebo 5mg vials
Two histidine solvent 5.2ml prefilled syringes
Two 13mm vial adaptors
Dosing/compunding Card.
Storage temperature: 2°-25° Celsius (36°-77° Fahrenheit) per USP <659>
Expiration date is available in WebDCU™ at https://webdcu.musc.edu.
Use as directed per study protocol.
Caution: New Drug - Limited by Federal Law to Investigational Use Only
Repackaged by StrokeNet NCC Central Pharmacy University of Cincinnati
Holmes Hospital Room 1209. 200A Albert Sabin Way ML 0405 Cincinnati. OH 45267-0405

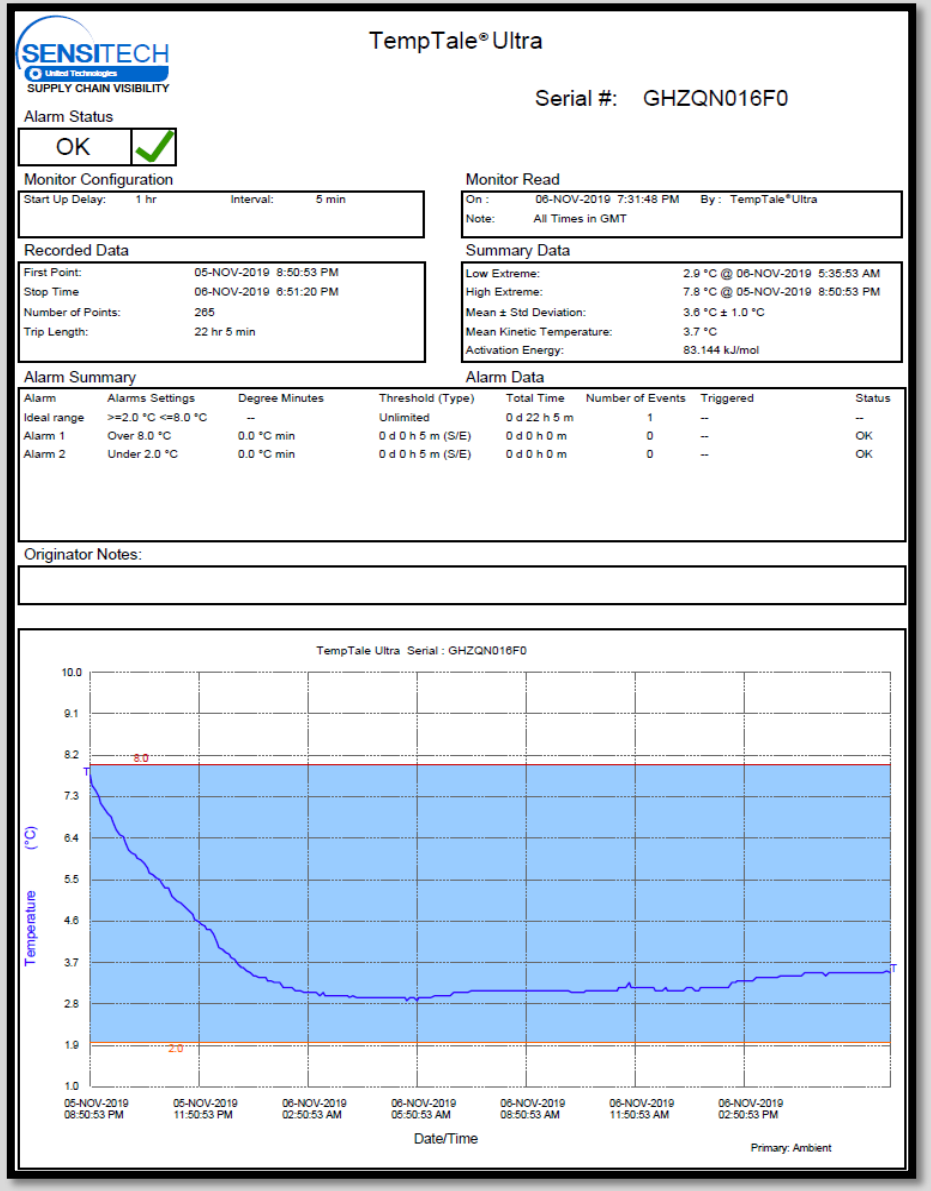
US kit label

- Country-specific **blinded kit labels**
- Kits are tampered evident sealed**. <u>It is required not</u>** to break the tamper evident seal until the kit is dispensed

Study Drug Receipt

- The initial study drug shipment will contain a total of two study drug kits to sites with one enrolling location (ED or MSU) and four study drug kits to sites that have two enrolling locations (ED+MSU) or 2 EDs
- Upon receipt of the drug shipment, the CPS will verify the receipt of the study drug kit(s) against the packing slip
- The CPS will review the temperature data from the logger and confirm that the study drug did not experience any temperature excursions in transit (next slide)
- Study drug kits should not be dispensed until received into WebDCU™ **and** site is released to enroll

Example Data Logger Report



SENSITECH
United Technologies
SUPPLY CHAIN VISIBILITY

TempTale® Ultra

Serial #: GHZQN016F0

Alarm Status

OK

Monitor Configuration

Start Up Delay:	1 hr	Interval:	5 min

Monitor Read

On :	06-NOV-2019 7:31:48 PM	By :	TempTale®Ultra
Note:	All Times in GMT		

Recorded Data

First Point:	05-NOV-2019 8:50:53 PM
Stop Time	06-NOV-2019 6:51:20 PM
Number of Points:	265
Trip Length:	22 hr 5 min

Summary Data

Low Extreme:	2.9 °C @ 06-NOV-2019 5:35:53 AM
High Extreme:	7.8 °C @ 05-NOV-2019 8:50:53 PM
Mean ± Std Deviation:	3.6 °C ± 1.0 °C
Mean Kinetic Temperature:	3.7 °C
Activation Energy:	83.144 kJ/mol

Alarm Summary

Alarm Data

Alarm	Alarms Settings	Degree Minutes	Threshold (Type)	Total Time	Number of Events	Triggered	Status
Ideal range	>=2.0 °C <=8.0 °C	--	Unlimited	0 d 22 h 5 m	1	--	--
Alarm 1	Over 8.0 °C	0.0 °C min	0 d 0 h 5 m (S/E)	0 d 0 h 0 m	0	--	OK
Alarm 2	Under 2.0 °C	0.0 °C min	0 d 0 h 5 m (S/E)	0 d 0 h 0 m	0	--	OK

Originator Notes:

1. Once the data logger arrives at the CPS ➡ stop the data logger by pressing the red STOP button for 1-3 seconds until the stop sign logo appears in the top right corner of the LCD display.

2. Insert the data logger into a USB port of a computer at the CPS.

3. View the PDF temperature data log and review the data log for temperature excursions

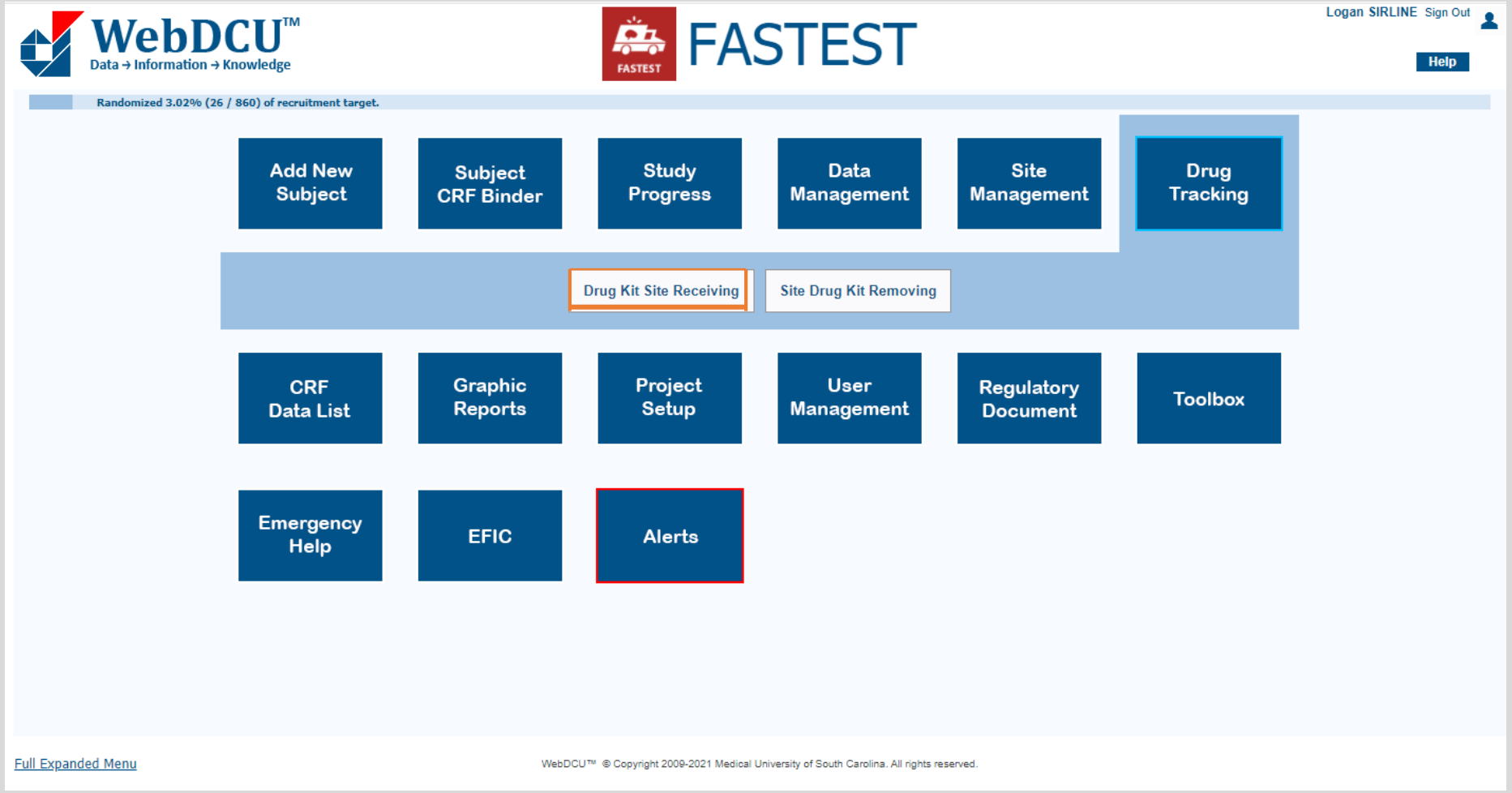
4. Print and file the temperature data log in the FASTEST trial binder to be available during monitoring visits

5. Once the data has been retrieved from the logger and the temperature curve is printed, the temperature logger can be disposed of per the institution's policy.

6. If **NO** temperature excursions or discrepancies are identified, the CPS will confirm receipt of all study drug kits in WebDCU™ Drug Tracking>Drug Receiving

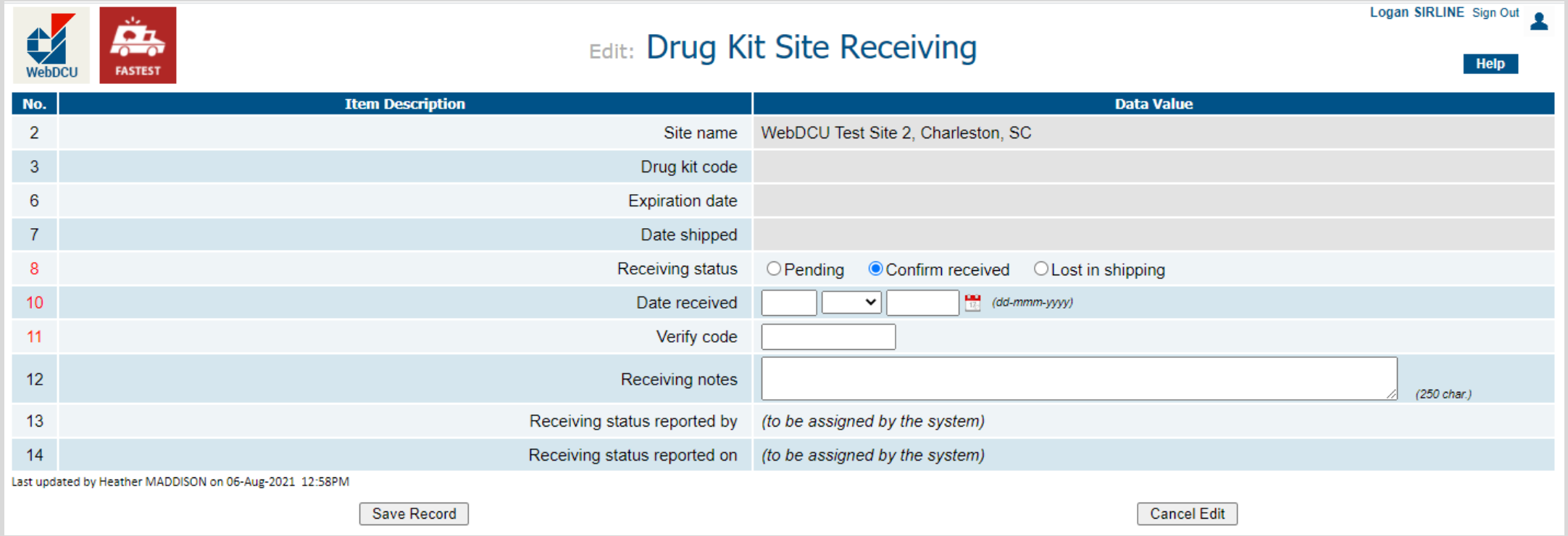
FASTEST

Drug Tracking



FASTEST

Receiving Drug



WebDCU FASTEST

Logan SIRLINE Sign Out

Edit: Drug Kit Site Receiving

Help

No.	Item Description	Data Value
2	Site name	WebDCU Test Site 2, Charleston, SC
3	Drug kit code	
6	Expiration date	
7	Date shipped	
8	Receiving status	○ Pending ◉ Confirm received ○ Lost in shipping
10	Date received	(dd-mmm-yyyy)
11	Verify code	
12	Receiving notes	(250 char.)
13	Receiving status reported by	*(to be assigned by the system)*
14	Receiving status reported on	*(to be assigned by the system)*

Last updated by Heather MADDISON on 06-Aug-2021 12:58PM

Save Record Cancel Edit

- If study drug kit(s) are not received into WebDCU™ **within 3 days** of shipment, the CPS will receive an automated email notification prompting them to receive the study drug kit(s) in WebDCU™

FASTEST

Study Medication Storage/Shipping Conditions

NOVO

- Novo will be shipping to the Central Pharmacy Depots at 2-8°C

NCC StrokeNet Pharmacy

- **Storage and shipping :** Study medication stored and will be shipped refrigerated.

Clinical Preforming Sites

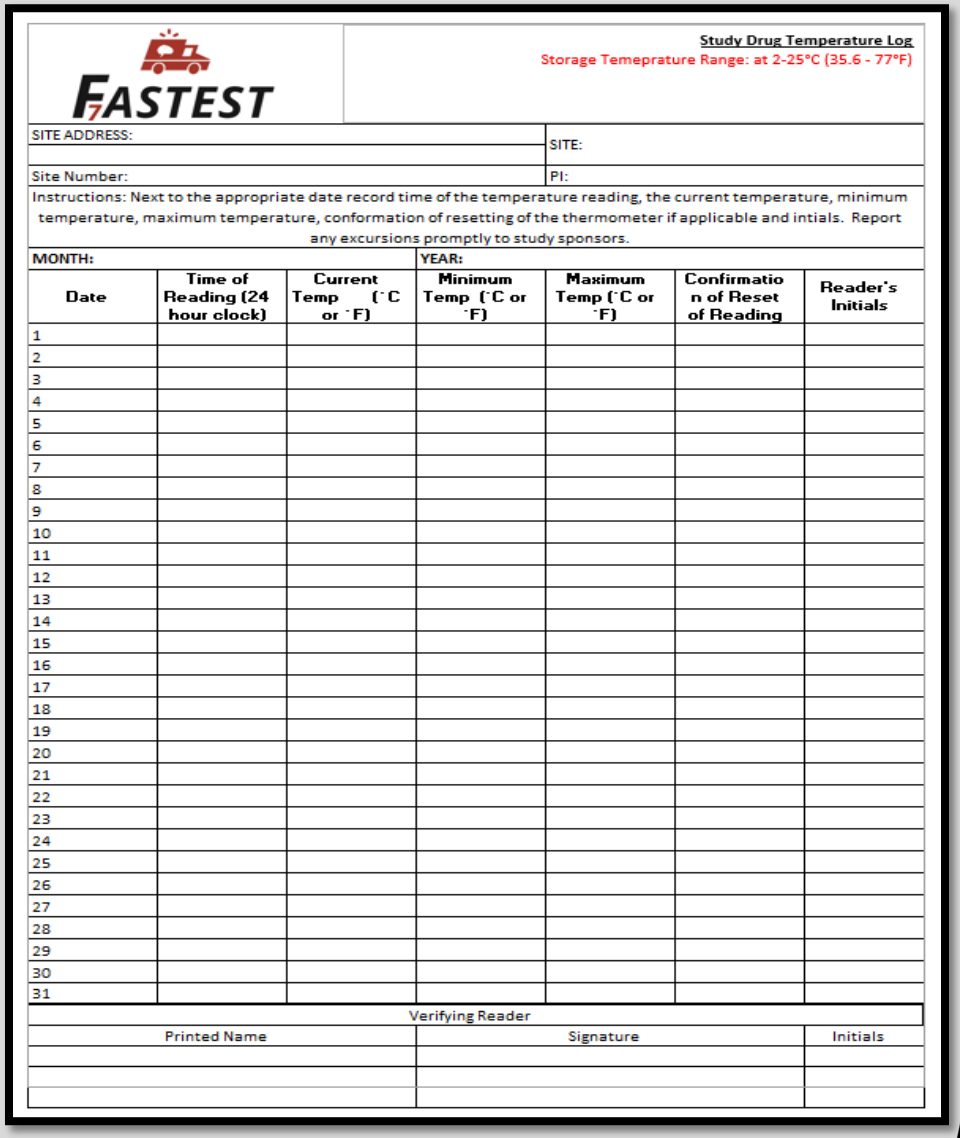
- Storage: Study medication can be stored (without preference) at room temperature or refrigerated, however, temperature MUST be continuously monitored.
- The permitted range for US : 35.6- 77°F
- Sample temperature monitoring logs will be provided and available in WebDCU™
  - Toolbox>Project Documents

FASTEST

Temperature Monitoring Log Example

CPSs are required to **maintain continuous temperature monitoring** logs at each enrolling location

Sample temperature monitoring logs will be provided and available in WebDCU™
Toolbox>Project Documents



FASTEST

Study Drug Temperature Log
Storage Temeprature Range: at 2-25°C (35.6 - 77°F)

SITE ADDRESS:	SITE:
Site Number:	PI:

Instructions: Next to the appropriate date record time of the temperature reading, the current temperature, minimum temperature, maximum temperature, conformation of resetting of the thermometer if applicable and intials. Report any excursions promptly to study sponsors.

MONTH:			YEAR:			
Date	Time of Reading (24 hour clock)	Current Temp (°C or °F)	Minimum Temp (°C or °F)	Maximum Temp (°C or °F)	Confirmation of Reset of Reading	Reader's Initials
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
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27						
28						
29						
30						
31						

Verifying Reader		
Printed Name	Signature	Initials

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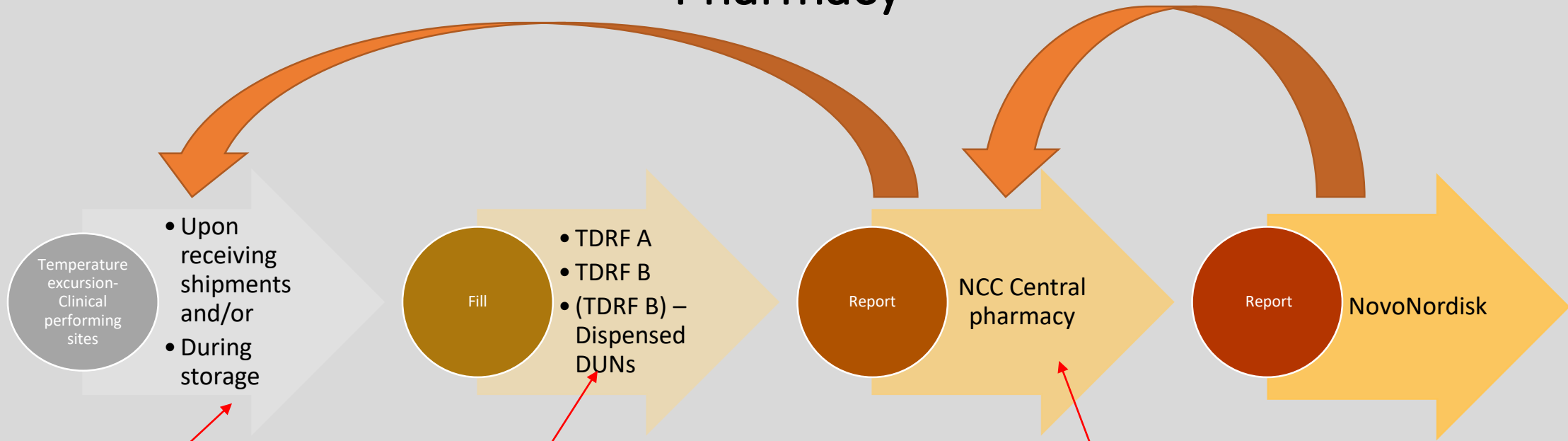
Temperature Excursions

A temperature excursion occurs when **in-transit or on-site drug storage** temperatures fall outside of acceptable temperature ranges.

- A temperature excursion should be reported if storage temperature falls below 2 ° C (35.6 ° F) and/or rises above 25 ° C (77 ° F).
- US Pharmacopeia (USP) rounding rules does apply for the temperature excursion. i.e., 1.5 ° C is rounded up to 2 ° C and 25.4 24.4 ° C is rounded down to 25° C. Both examples are **not** a reportable excursion
- Any temperature excursion affecting FASTEST study drug kits must be reported immediately, preferably within **48 hours** of occurrence.

In Transit Temperature Excursion: If study drug experiences a temperature excursion in-transit, do NOT receive kits into WebDCU™ inventory. Study drug kits are available for randomization once they are marked as received in WebDCU™.

Reporting Temperature Excursions to Novo Nordisk A/S at **Site Pharmacy**



Quarantine in the appropriate storage temperature

(TDRF B) – Dispensed DUNs:
only to be used in the rare cases where a temperature deviation occurs, but action is not immediately taken to resolve this, and products are dispensed to patients

@ FASTESTtrialRX@uc.edu

Temperature Deviations

Temperature Deviation Report Form A – Site

Instructions:

- Please complete the form in its entirely. Fields marked with * are mandatory.
- Green text is guidance text and should be deleted before use.
- Email this form and all relevant temperature logs to NCC Central Pharmacy, at FASTESTtrialRX@ucmail.uc.edu
- US Pharmacopeia (USP) rounding rules apply for temperature excursions. i.e. 1.5°C is rounded up to 2°C and 8.4°C is rounded down to 8°C. Both examples are not a reportable excursion.

General information

*Trial ID: U1111-1201-0087/ FASTEST	*Site number:
*Country:	*Prioritisation date eg, next dispensing date or DBL date: Not known or N/A ☐
*Has the product affected by the deviation been dispensed to subjects?	Yes ☐ No ☐ If **no**, please complete Temperature Deviation Report Form B (**Page 2 of this document**) If **yes**, please complete Temperature Deviation Report Form B, Dispensed DUNs. (**Page 3 of this document**)
*Type of deviation Storage deviation : ☐ Attach graph/ logs Shipment deviation: ☐ Attach graph/ logs	Logger ID: Logging interval for storage temperature monitoring device Logger ID:

Description of the deviation

*Date/period of deviation Include time if relevant Start date/time: Stop date/time:	*Temperature Too warm: ☐ Too cold: ☐ compared to allowed temperature range Highest/lowest temperature:

Additional information: Only if relevant to the case evaluation, for example arrival time of the products if the temperature deviation is due to data logger not stopped upon arrival

Example: Above 30° for 45 min
Below 2° for 120 min

*It is confirmed that the products are stored, quarantined and within allowed temperature range.

Initials: Date:

- Fill in TDRF-A

Temperature Deviation Report Form B – Site

Green text is guidance text and should be deleted before use.

Please complete the form electronically and submit with the TDRF A. Fields marked with * *must* be completed.

Trial and site information

*Trial ID: U1201-0087/ FASTEST	*Site number: For example, "102"

Trial product information

*IWRS used	Yes ☐ No ☒
*If IWRS is used: Affected product status has been changed to "temporarily unavailable" in the IWRS.	Yes ☐ N/A ☒

Specific for deviations during shipment

* Shipment tracking no:	

*Please list all trial products involved in the deviation

*Product name	*Lot no/coded Lot no (if applicable)	*Kit (list all Kits for the specific lot)	*DUN/component code no (list all DUN for the specific batch)

Specific for deviations during storage

*Please list all trial products involved in the deviation

*Product name	*Lot no/coded lot no (if applicable)	*Shipment no	*Kit (list all kits for the specific lot)	*DUN/ component code no (list all DUN for the specific batch)

- Fill in TDRF-B

- Fill in TDRF-B, Dispensed DUNs

Temperature Deviation Report Form B, Dispensed DUNs – Site

Green text is guidance text and should be deleted before use.

Please complete the form electronically and submit with the TDRF A. Fields marked with * *must* be completed.

Trial and site information

*Trial ID: U1201-0087/ FASTEST	*Site number: For example "102"

*Please list all trial products involved in the deviation

*Product name	*Lot no/coded lot no (if applicable)	*Shipment no	*kit (list all Kits for the specific lot)	*DUN (list all DUNs for the specific kit)	*Date dispensed

Trial ID: U1201-0087/FASTEST
Site number: Unique description
Country:
Prioritisation date: Optional
Dispensed: Yes/No
Type: Storage/shipment
Logger ID: From Log or device
Description of deviation: From Log
Additional information: Optional
Write initials and date
Information from packs
Shipment no.: From Pack Slip

- The Temperature Excursion Report Form (TERF) - available in WebDCU™ Toolbox>Project Documents – submit for both storage and in transit excursions

What inside FASTEST kit?

Dosing/ compounding card

<u>Histidine Diluent box</u>
Containing two 5.2mL prefilled histidine syringes

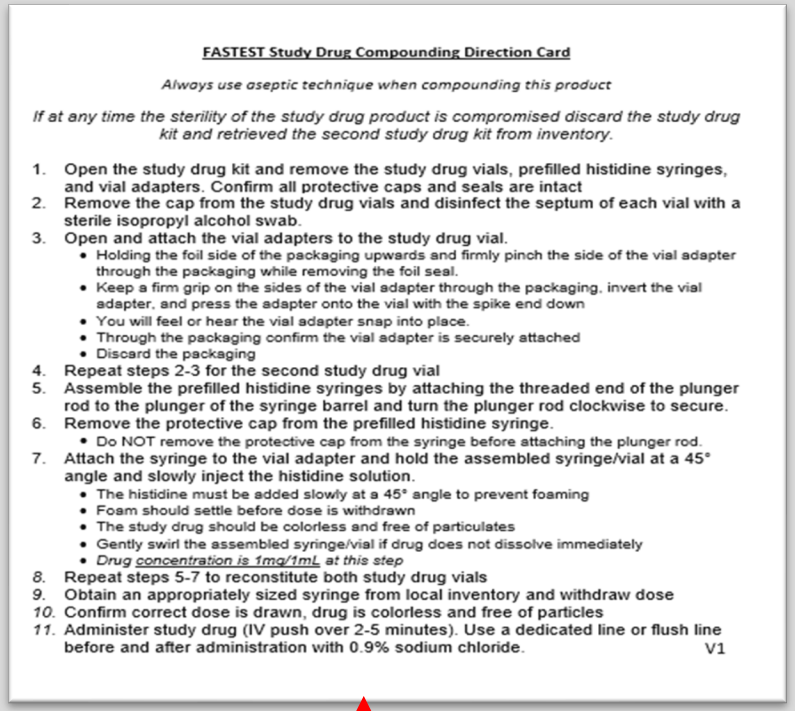
<u>rFVIIa Active or Placebo box</u>
Containing two 5 mg vials of lyophilized drug

The dun boxes containing histidine and rFVIIa will be referred to as kit components in WebDCU.

<u>13mm vial adapters</u>
Each kit must have <u>two</u> vial adapters.

FASTEST

Kit Component Boxes: Dosing/ compounding card



FASTEST Study Drug Compounding Direction Card

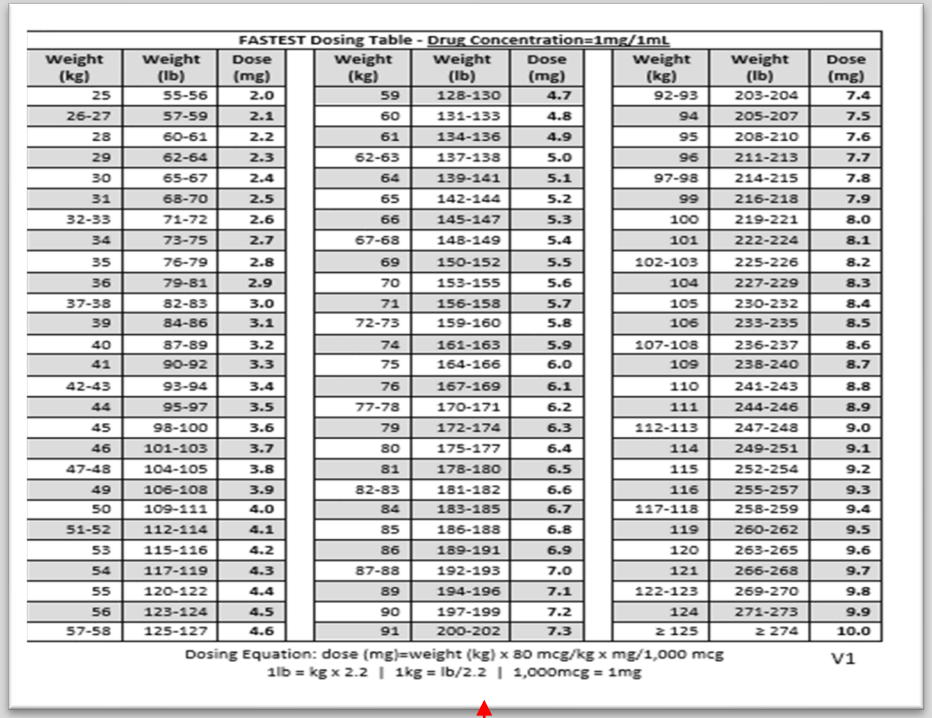
Always use aseptic technique when compounding this product

If at any time the sterility of the study drug product is compromised discard the study drug kit and retrieved the second study drug kit from inventory.

1. Open the study drug kit and remove the study drug vials, prefilled histidine syringes, and vial adapters. Confirm all protective caps and seals are intact
2. Remove the cap from the study drug vials and disinfect the septum of each vial with a sterile isopropyl alcohol swab.
3. Open and attach the vial adapters to the study drug vial.
   - Holding the foil side of the packaging upwards and firmly pinch the side of the vial adapter through the packaging while removing the foil seal.
   - Keep a firm grip on the sides of the vial adapter through the packaging, invert the vial adapter, and press the adapter onto the vial with the spike end down
   - You will feel or hear the vial adapter snap into place.
   - Through the packaging confirm the vial adapter is securely attached
   - Discard the packaging
4. Repeat steps 2-3 for the second study drug vial
5. Assemble the prefilled histidine syringes by attaching the threaded end of the plunger rod to the plunger of the syringe barrel and turn the plunger rod clockwise to secure.
6. Remove the protective cap from the prefilled histidine syringe.
   - Do NOT remove the protective cap from the syringe before attaching the plunger rod.
7. Attach the syringe to the vial adapter and hold the assembled syringe/vial at a 45° angle and slowly inject the histidine solution.
   - The histidine must be added slowly at a 45° angle to prevent foaming
   - Foam should settle before dose is withdrawn
   - The study drug should be colorless and free of particulates
   - Gently swirl the assembled syringe/vial if drug does not dissolve immediately
   - *Drug concentration is 1mg/1mL at this step*
8. Repeat steps 5-7 to reconstitute both study drug vials
9. Obtain an appropriately sized syringe from local inventory and withdraw dose
10. Confirm correct dose is drawn, drug is colorless and free of particles
11. Administer study drug (IV push over 2-5 minutes). Use a dedicated line or flush line before and after administration with 0.9% sodium chloride.

V1

Compounding instruction page



FASTEST Dosing Table - Drug Concentration=1mg/1mL

Weight (kg)	Weight (lb)	Dose (mg)	Weight (kg)	Weight (lb)	Dose (mg)	Weight (kg)	Weight (lb)	Dose (mg)
25	55-56	2.0	59	128-130	4.7	92-93	203-204	7.4
26-27	57-59	2.1	60	131-133	4.8	94	205-207	7.5
28	60-61	2.2	61	134-136	4.9	95	208-210	7.6
29	62-64	2.3	62-63	137-138	5.0	96	211-213	7.7
30	65-67	2.4	64	139-141	5.1	97-98	214-215	7.8
31	68-70	2.5	65	142-144	5.2	99	216-218	7.9
32-33	71-72	2.6	66	145-147	5.3	100	219-221	8.0
34	73-75	2.7	67-68	148-149	5.4	101	222-224	8.1
35	76-79	2.8	69	150-152	5.5	102-103	225-226	8.2
36	79-81	2.9	70	153-155	5.6	104	227-229	8.3
37-38	82-83	3.0	71	156-158	5.7	105	230-232	8.4
39	84-86	3.1	72-73	159-160	5.8	106	233-235	8.5
40	87-89	3.2	74	161-163	5.9	107-108	236-237	8.6
41	90-92	3.3	75	164-166	6.0	109	238-240	8.7
42-43	93-94	3.4	76	167-169	6.1	110	241-243	8.8
44	95-97	3.5	77-78	170-171	6.2	111	244-246	8.9
45	98-100	3.6	79	172-174	6.3	112-113	247-248	9.0
46	101-103	3.7	80	175-177	6.4	114	249-251	9.1
47-48	104-105	3.8	81	178-180	6.5	115	252-254	9.2
49	106-108	3.9	82-83	181-182	6.6	116	255-257	9.3
50	109-111	4.0	84	183-185	6.7	117-118	258-259	9.4
51-52	112-114	4.1	85	186-188	6.8	119	260-262	9.5
53	115-116	4.2	86	189-191	6.9	120	263-265	9.6
54	117-119	4.3	87-88	192-193	7.0	121	266-268	9.7
55	120-122	4.4	89	194-196	7.1	122-123	269-270	9.8
56	123-124	4.5	90	197-199	7.2	124	271-273	9.9
57-58	125-127	4.6	91	200-202	7.3	≥ 125	≥ 274	10.0

Dosing Equation: dose (mg)=weight (kg) x 80 mcg/kg x mg/1,000 mcg

1lb = kg x 2.2 | 1kg = lb/2.2 | 1,000mcg = 1mg

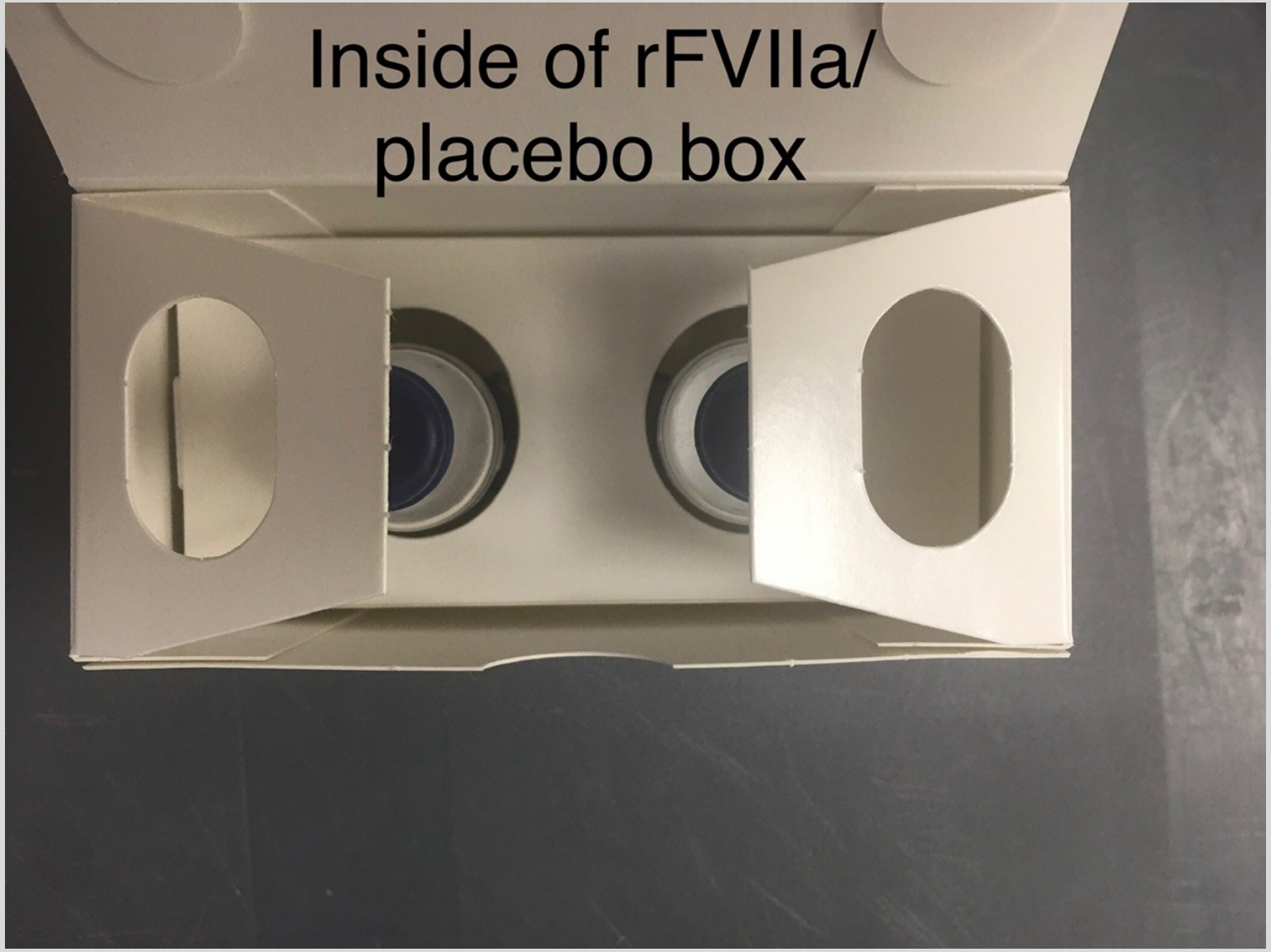
V1

Dosing chart (US and Canada) page

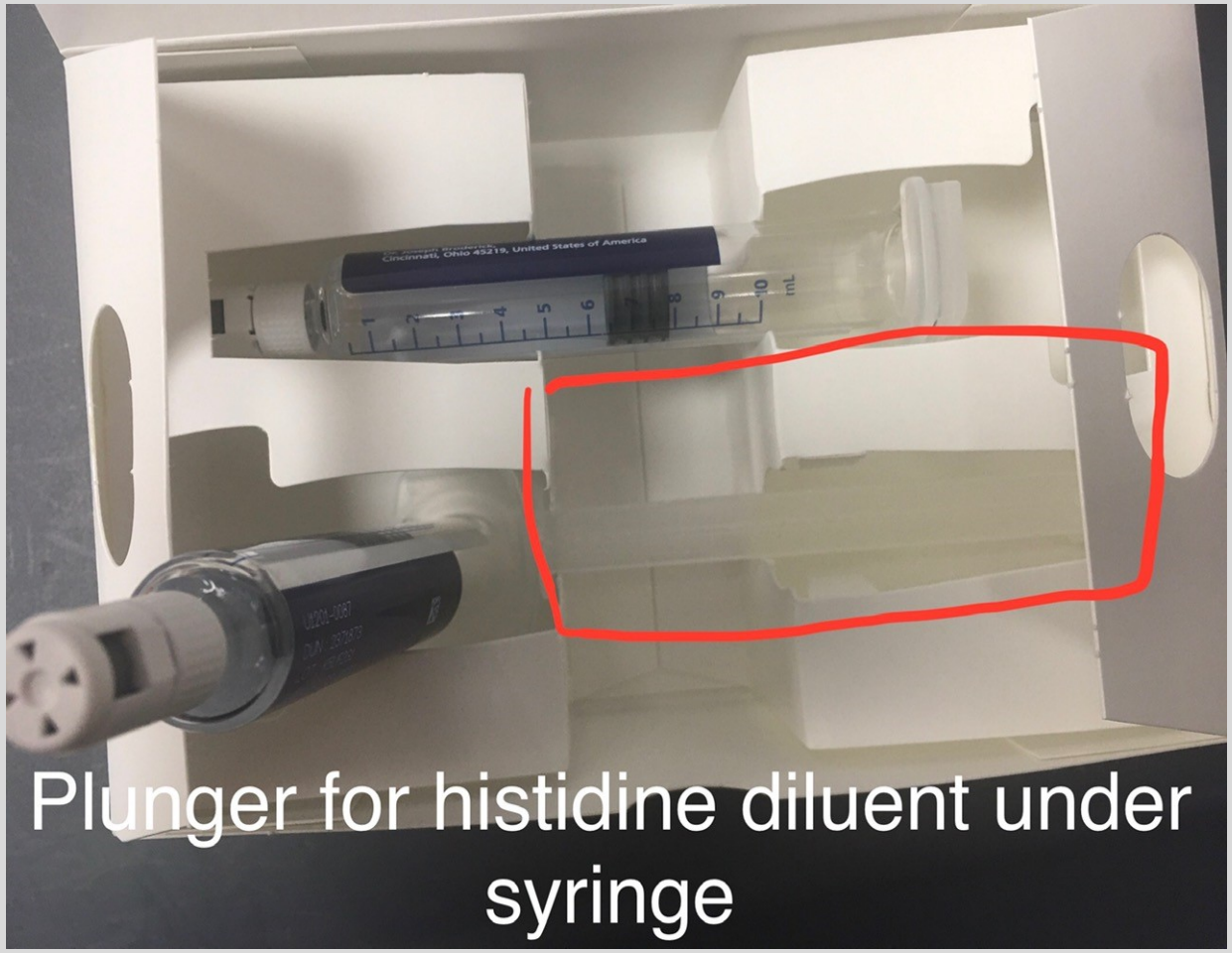
- 5X5 two-sided card added to each kit

FASTEST

Inside the shipment from Novo Nordisk-Inside the rFVIIa/placebo Dun Box



Inside the shipment from Novo Nordisk-Inside the Histidine Dun Box



Accountability & Chain of Custody

- CPS with two enrolling locations with four kits; the CPS can determine how many study drug kits to store for each enrolling location; WebDCU™ will not provide this information
- It is recommended to keep **two kits at each enrolling location**, so a back-up kit is available, if needed.
- CPSs will be responsible to complete the chain of custody form each time a study drug kit is transferred internally from one location to another.
- "chain of custody" and accountability log which serves as a tracking document to track the investigational product from the time it leaves the manufacturer until the time it is used by a subject, destroyed, or returned back to the StrokeNet pharmacy

Don't break the chain!

- CPSs are required to maintain study drug accountability records and temperature monitoring logs
  - CPSs may use their institution's electronic inventory system or use the provided paper logs (WebDCU™ Toolbox>Project Documents)

Drug Accountability

Investigational product (IP) Drug Accountability Log
Protocol Number: U1111-1201-0087

Site Name:
Site Number:
Principal Investigator:

Overall inventory on site				Subject level drug accountability						Drug destruction	
Date received	Total # of kits received	Balance of drug kits in stock	Site personnel (initials/date)	Pt initials	Date dispensed	Kit code	Total volume prepared (mL)	Total volume administered (mL)	Dispenser (initials/date)	# of vials destroyed	Site personnel (initials/date)

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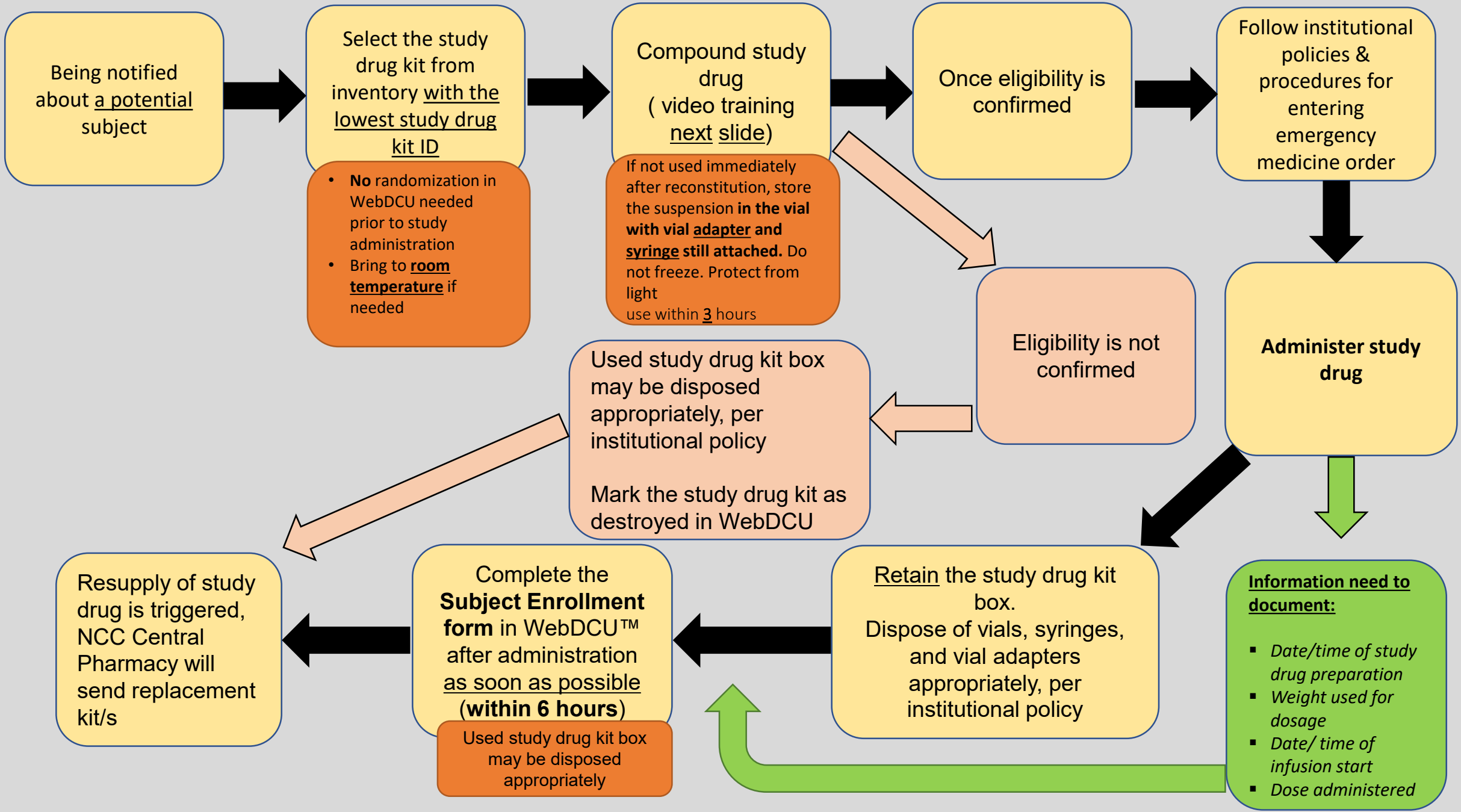
Chain of Custody

Investigational product (IP) Chain of Custody
Protocol Number: U1111-1201-0087

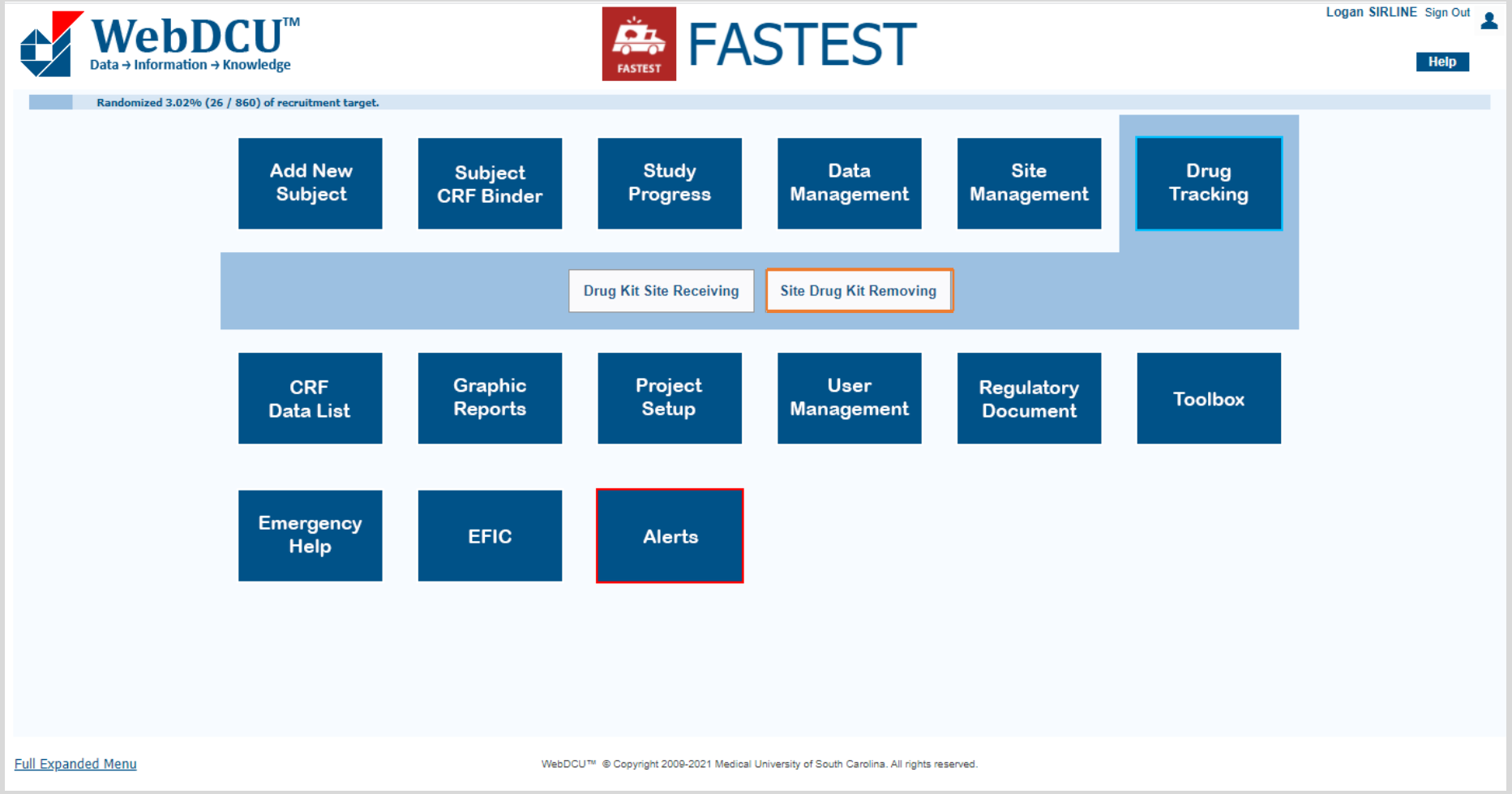
Instructions: *Any exchange of FASTEST Kits should be documented on this form*

Transition From *(Location of Medication Storage)*	**Transition To** *(Location of Medication Storage)*	**Date/Time**	**Received by (initials)**	**# of Kits**	**Kit Code(s)**	**The Study Kit/s is/are received in good condition (initials/date)**

Study drug dispensing workflow



Drug Tracking



FASTEST

rFVIIa for Acute Hemorrhagic Stroke Administered at Earliest Time (FASTEST)

Compounding Video

Training prepared by : Noor Sabagha R.PH., MPH
Hirut Akalu CPhT, CSPT

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MUSC Medical University of South Carolina

UNIVERSITY OF Cincinnati

MEMORIAL HERMANN Clinical Innovation & Research Institute

Northwestern Medicine Feinberg School of Medicine

IMPORTANT

- The prefilled glass syringe is **compatible with a standard Luer-lock connector**

- However, some needleless connectors for intravenous catheters are incompatible with the glass diluent syringes (for example, certain connectors with an internal spike, such as Clave®/MicroClave®, InVision-Plus®, InVision-Plus CS®, InVision-Plus® Junior®, Bionector®), and their use can damage the connector and affect administration.

- To administer study drug through incompatible needleless connectors, withdraw reconstituted product into a standard 10 mL sterile Luer-lock plastic syringe.

Study Drug Requests

- WebDCU™ study drug shipment requests will automatically be sent to the StrokeNet NCC Central Pharmacy when:
- Sites that released to receive study.
- Subjects are randomized (complete Subject Enrollment form in WebDCU™ within 6 hr. of drug administration)
- Study drug is damaged/expired
  - Drug Request will be sent to the NCC Central Pharmacy 14 days prior to kit expiration

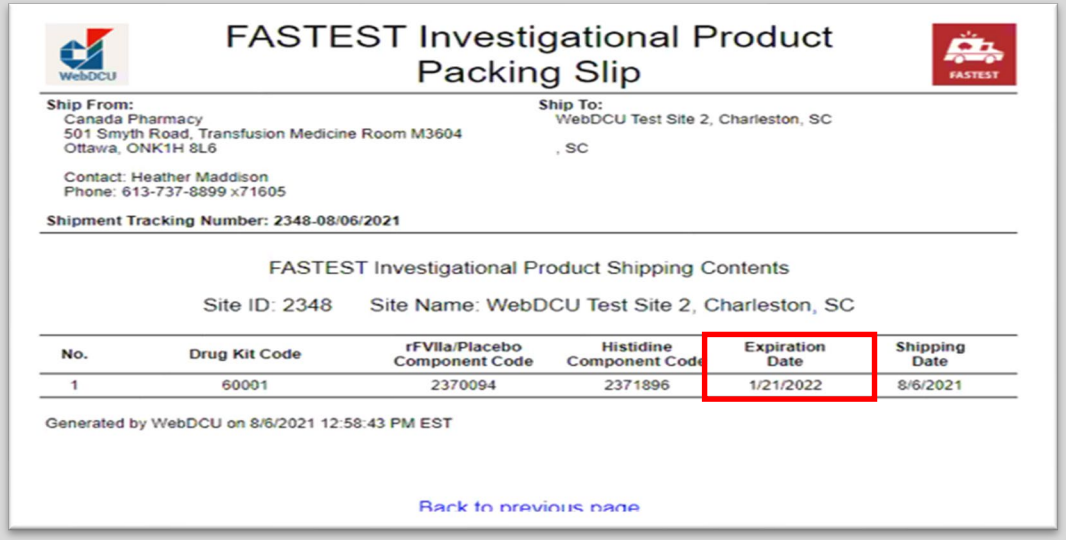
Study Drug Kit Expiration

Study drug kit expiration dates are available in 2 locations:

- FASTEST study drug packing slip
- WebDCU™ (Drug Tracking Tab> Site Drug Kit Removing)
- Will NOT be on study drug kit labels

CPSs will receive emails from WebDCU™ and the NCC Central Pharmacy when kits are nearing their expiration

- Emails will contain instructions on how to handle expiring kits and when to expect replacement kits
- Replacement kits will be sent before current inventory expirations to prevent CPSs from running out of study drug inventory



FASTEST Investigational Product Packing Slip

Ship From:
Canada Pharmacy
501 Smyth Road, Transfusion Medicine Room M3604
Ottawa, ONK1H 8L6

Contact: Heather Maddison
Phone: 613-737-8899 x71605

Ship To:
WebDCU Test Site 2, Charleston, SC
, SC

Shipment Tracking Number: 2348-08/06/2021

FASTEST Investigational Product Shipping Contents

Site ID: 2348 Site Name: WebDCU Test Site 2, Charleston, SC

No.	Drug Kit Code	rFVIIa/Placebo Component Code	Histidine Component Code	Expiration Date	Shipping Date
1	60001	2370094	2371896	1/21/2022	8/6/2021

Generated by WebDCU on 8/6/2021 12:58:43 PM EST

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Study Drug Destruction & Return

CPSs should follow their institutional policy regarding drug destruction protocol

The StrokeNet NCC Central pharmacy can accept returns for destruction if a CPSs institutional policy requires returning the damage or expired drug kits

Follow the steps below to return study drug to the StrokeNet NCC Central Pharmacy

Study Drug Return Form must be completed and returned with the shipment

Available on WebDCU™ - Toolbox>Project Documents

Returns should be addressed and shipped to the StrokeNet NCC Central Pharmacy via the CPSs preferred postal carrier

Return cost will be at the expense of the CPS

Package tracking information must be provided to StrokeNet NCC Central Pharmacy via email

Temperature monitoring is NOT required for returns

Subject identifiers must be removed from returns

Study Drug Destruction & Return

Instructions to the Pharmacist/Designee:
1. Type or handwrite clearly all information.
2. Complete all sections (except *StrokeNet NCC Central Pharmacy Use Only* section).
3. Print this form (if needed).
4. Sign and date this form.
5. Keep a copy of form for your records.
6. Enclose this form with study products and return via preferred shipping method to the StrokeNet NCC Central Pharmacy.
7. Pack study products properly to prevent breakage and/or leakage.

Study Drug Return Form

Protocol Number: U1111-1201-0087

FASTEST

Return to:

StrokeNet NCC Central Pharmacy

University of Cincinnati
Holmes Hospital Room 1209
200 Albert Sabin Way ML 0405
Cincinnati, OH 45267-0405
Phone: 513-584-3166
Fax: 513-584-0091
Email: FASTESTtrialRX@ucmail.uc.edu

Site Name	Site Number
Designee/Pharmacist Name	

Protocol Number	Kit Code	Full	Partial	Manufacturer	Lot Number	Comment(s)

Pharmacy/Site Mailing Address	Designee/Pharmacist Name	Contact Phone Number
	Designee/Pharmacist Signature	Date

StrokeNet NCC Central Pharmacy Use Only

Protocol Number/Study Product Name	Date Processed	Signature of Reviewing Official

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When you think about **FASTEST** remember …….

- Prepare study drug as **FAST** as you can (prior to study drug administration, no randomization in WebDCU needed)
- Complete the Subject Enrollment form in WebDCU as **FAST** as possible (within 6 hours post study drug administration) for …
- StrokeNet pharmacy to resupply you with study drug as **FAST** as they can.

Questions?

Please visit WebDCU™ for a copy of the FASTEST Study Drug Procedure Manual

Toolbox>Project Documents