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

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Prior to Readiness call/SIV

Complete site Pharmacy regulatory

Receive study drugs

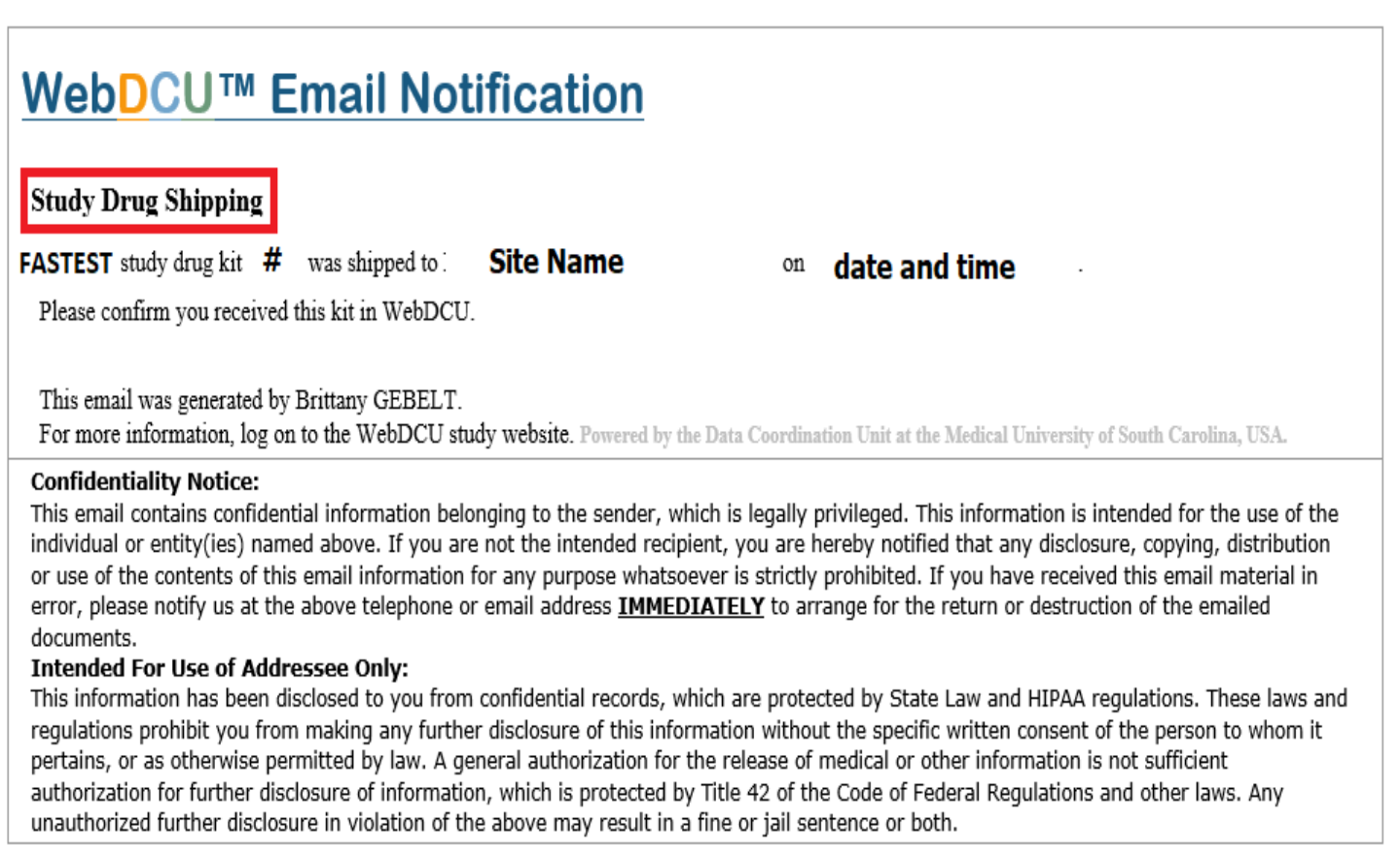
Readiness call/SIV

(Ask questions!)

Site Pharmacy Regulatory in WebDCU™

- Drug Destruction Policy/SOP or explaining note to file must be provided by site to NCVC Central Pharmacy and uploaded into WebDCU™
- Site pharmacy license, or in absence of a pharmacy license, a completed and signed FASTEST Pharmacy Certification Attestation, with or without a site's Quality Assurance certification must be entered into WebDCU™.
- Drug shipping address must be entered into WebDCU™ .
- The DOA includes at least one qualified person with pharmacy privileges
- When a Clinical Performing Site (CPS) is released to receive study drug, an initial study drug shipment will automatically be submitted to NCVC Central Pharmacy by WebDCU™
- NCVC Central Pharmacy ships study drug kits few days prior to readiness call/SIV to be received by site 1-2 days prior to call/SIV
- NCVC Central Pharmacy will ship study drug kits Monday through Wednesday for next day delivery. No shipments will take place for receipt on 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:
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- 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 2 study drug kits in the shipment, the CPS will receive an individual email for each kit (2 emails).
- If arrival of shipment appears delayed, CPS should contact the NCVC Central Pharmacy via Email: fastest.jpharm@ncvc.go.jp .NCVC Central Pharmacy can track shipment via SAGAWA EXPRESS®. number and will forward status to CPS.

FASTEST

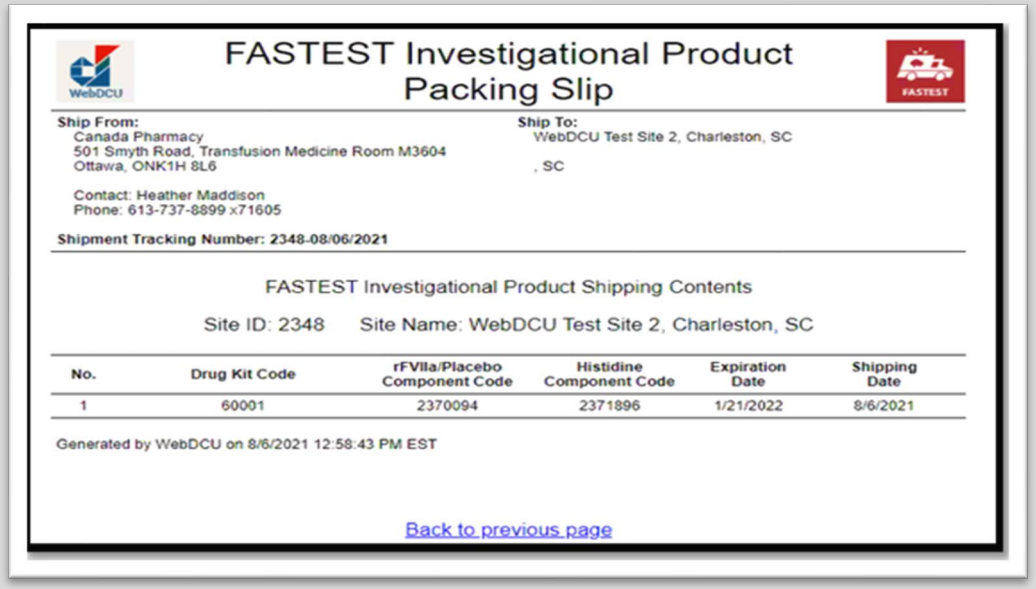
Study Drug Packaging and Packing Slip

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 2-10°C (35.6-50°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

Study Drug Kit ID

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
19.5 x 18.5 x 7.5 cm

FASTEST試験 （特定臨床研究）

品名	遺伝子組換え活性型血液凝固第Ⅶ因子製剤（rFⅦa）またはプラセボ
内容物	薬剤バイアル（rFⅦa 5mgまたはプラセボ）（2バイアル） 専用溶解用液（ヒスチジン溶液）（2シリンジ）
製造番号	
使用期限	
溶解液製造番号	
貯法	（1-30 ℃）で保存
規制区分	生物由来製品（rFⅦa）

研究代表医師
国立研究開発法人 国立循環器病研究センター 副院長 豊田一則
〒564-8565 大阪府吹田市岸部新町6番1号

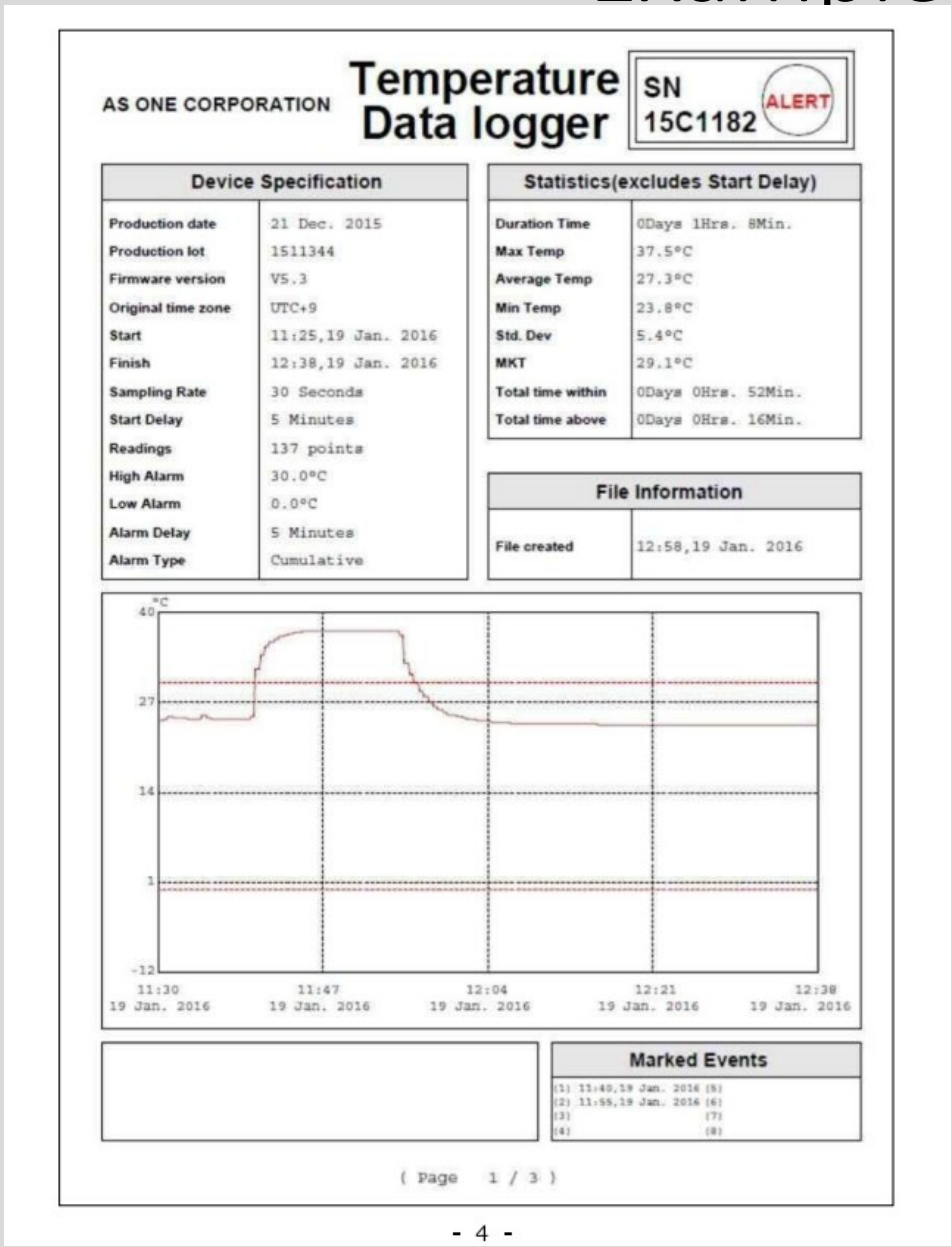
Japanese kit label

- Country-specific **blinded kit labels**
- Kits are tampered evident sealed. **It is required not** to break the tamper evident seal until the kit is dispensed
- Two lot numbers will be printed on the kit label (rFVIIa/placebo as well as histidine lot no.)

Study Drug Receipt

- The initial study drug shipment will contain a total of two study drug kits to sites.
- 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 USB logger and confirm that the study drug did not experience any temperature excursions in transit (next slide)
- Study drug kits cannot be dispensed until received into WebDCU™ **and** site is released to enroll

Example Data Logger Report



AS ONE CORPORATION

Temperature Data logger

SN 15C1182 ALERT

Device Specification	
Production date	21 Dec. 2015
Production lot	1511344
Firmware version	V5.3
Original time zone	UTC+9
Start	11:25,19 Jan. 2016
Finish	12:38,19 Jan. 2016
Sampling Rate	30 Seconds
Start Delay	5 Minutes
Readings	137 points
High Alarm	30.0°C
Low Alarm	0.0°C
Alarm Delay	5 Minutes
Alarm Type	Cumulative

Statistics(excludes Start Delay)	
Duration Time	0Days 1Hrs. 8Min.
Max Temp	37.5°C
Average Temp	27.3°C
Min Temp	23.8°C
Std. Dev	5.4°C
MKT	29.1°C
Total time within	0Days 0Hrs. 52Min.
Total time above	0Days 0Hrs. 16Min.

File Information	
File created	12:58,19 Jan. 2016

Marked Events

(Page 1 / 3)

- 4 -

1. Once the data logger arrives at the CPS ➡ stop the data logger by pressing the red STOP button for 2 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.

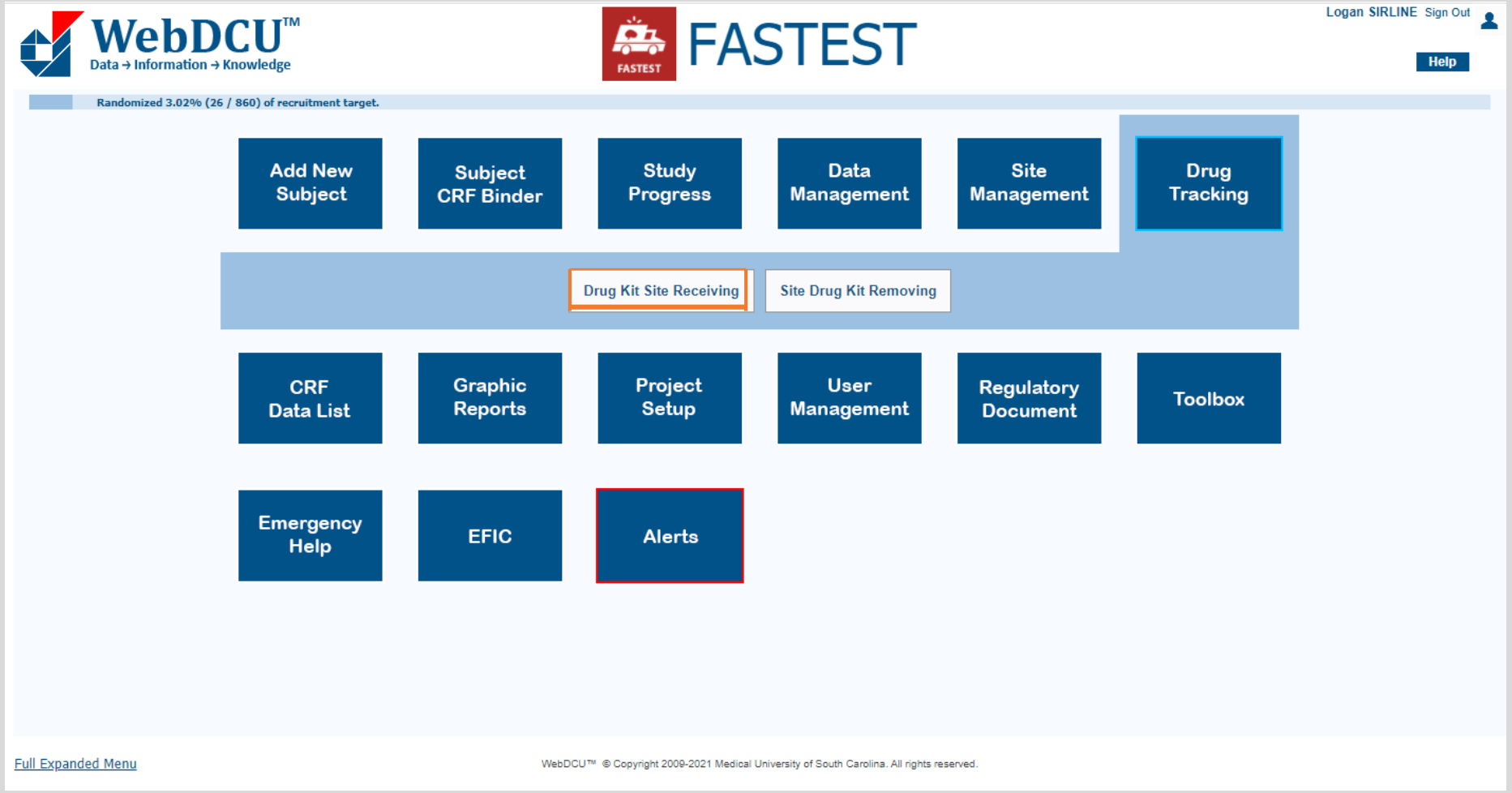
3. View the PDF temperature data log and review the data log for temperature excursions.

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

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

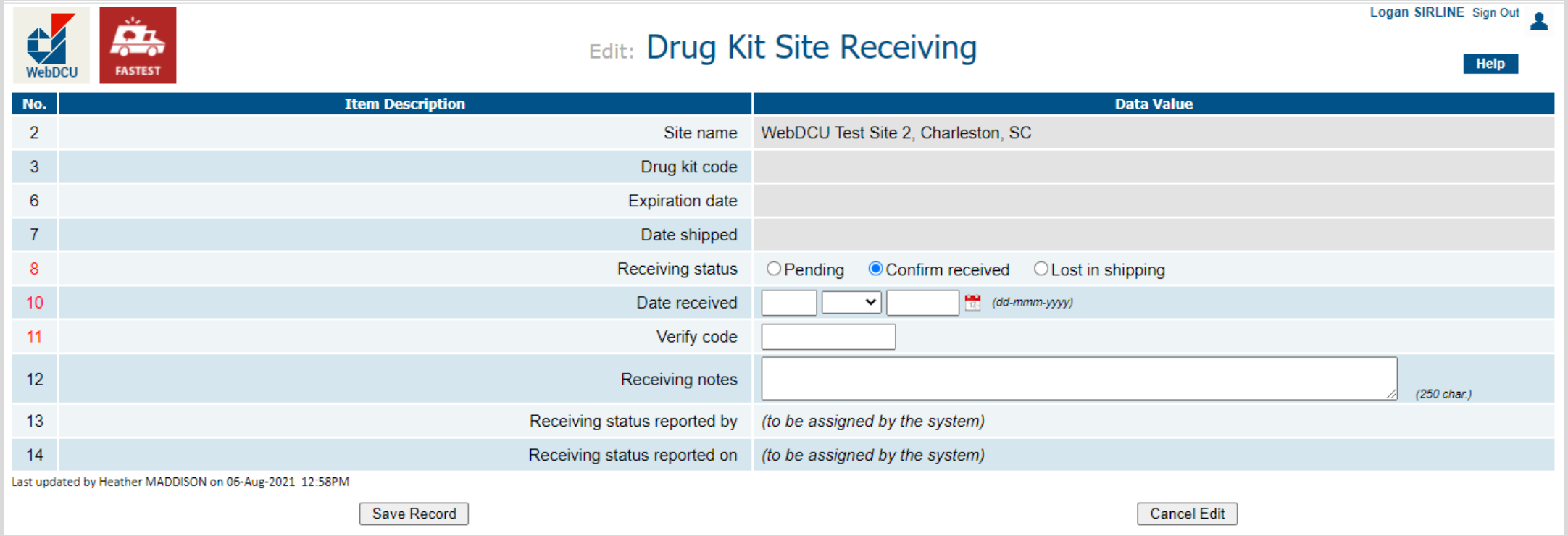
FASTEST

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 Nordisk

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

NCVC Central Pharmacy

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

Clinical Performing Sites

- Storage: Study medication can be stored (without preference) at room temperature or refrigerated, however, temperature MUST be continuously monitored.
- The permitted range for Japan: 1-30°C
- Sample temperature monitoring logs will be provided and available in WebDCU™
  - Toolbox>Project Documents

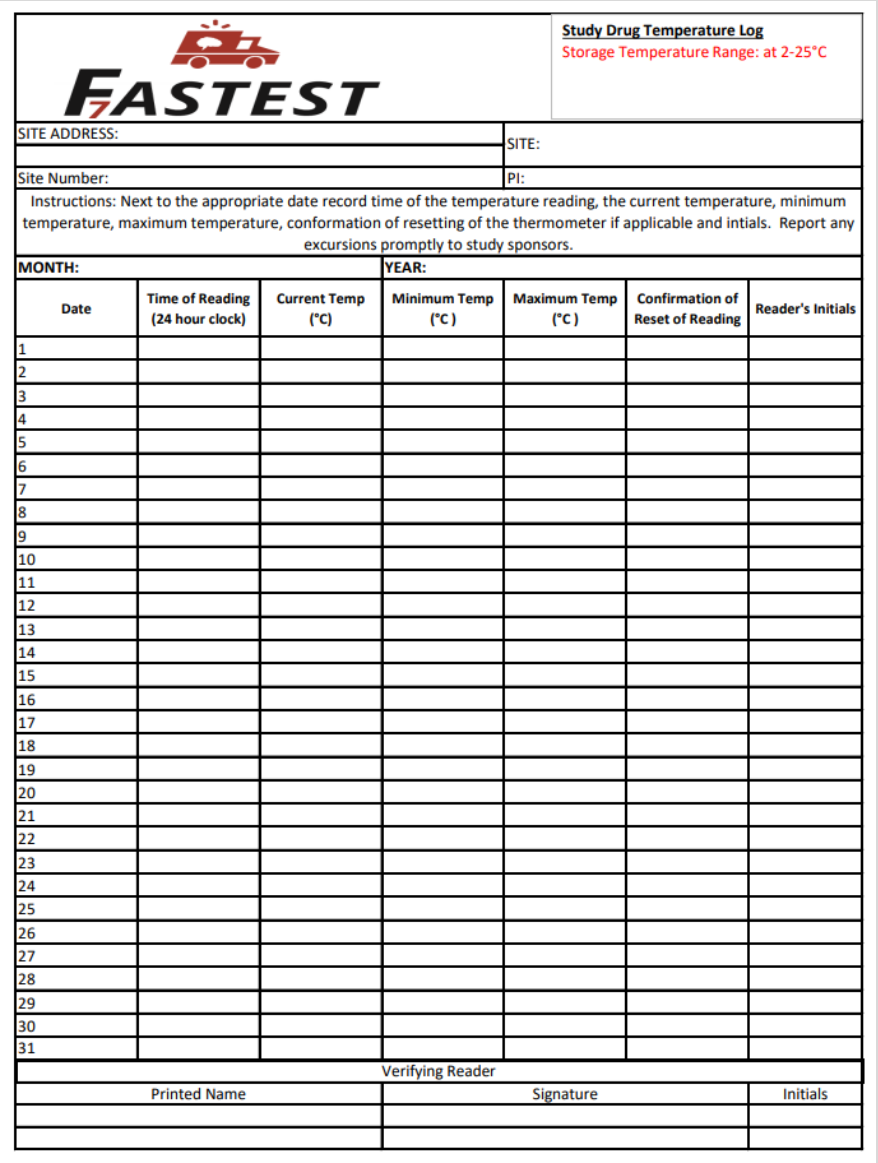
FASTEST

Temperature Monitoring Log Example

CPSs are required to **maintain continuous temperature monitoring** logs at <u>each</u> enrolling location

Sample temperature monitoring logs will be provided and available in WebDCU™

Toolbox>Project Documents



FASTEST

Study Drug Temperature Log

Storage Temperature Range: at 2-25°C

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)	Minimum Temp (°C)	Maximum Temp (°C)	Confirmation of Reset of Reading	Reader's Initials
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
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24						
25						
26						
27						
28						
29						
30						
31						

Verifying Reader		
Printed Name	Signature	Initials

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FASTEST

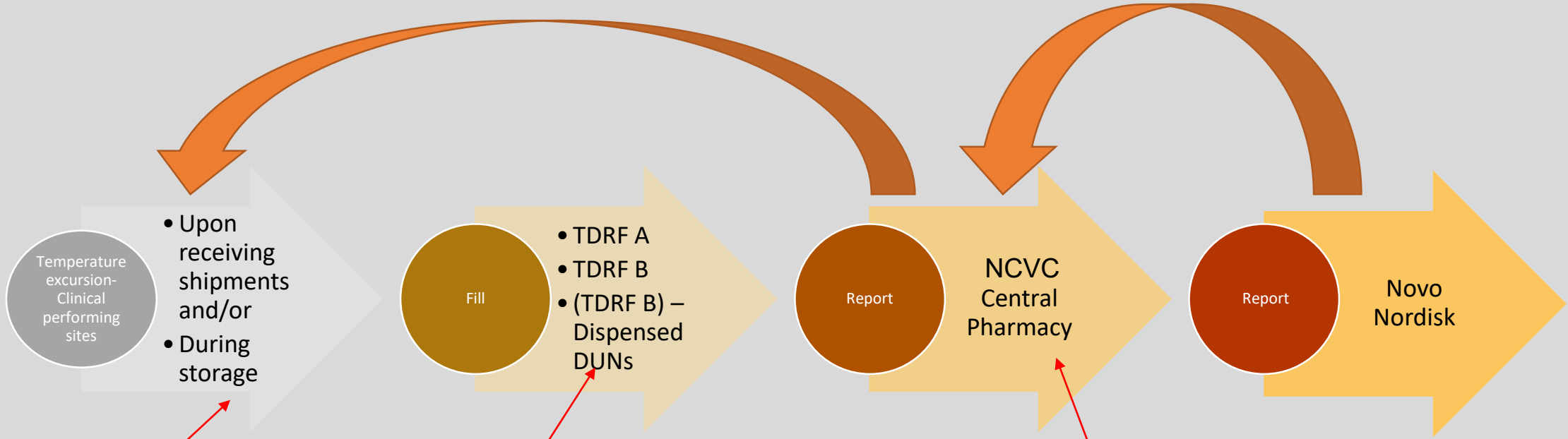
Temperature Excursions

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

- A temperature excursion should be reported if storage temperature falls below 1°C and/or rises above 30°C.
- 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**



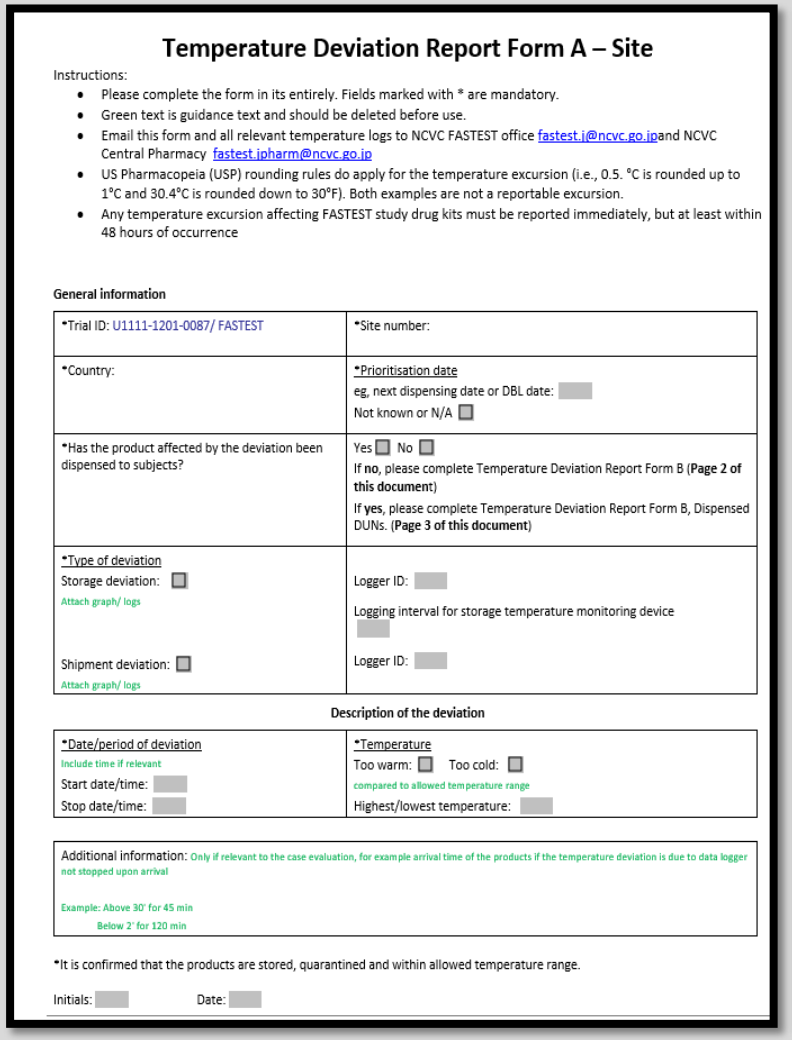
Quarantine in the appropriate storage temperature

(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

fastest.jpharm@ncvc.go.jp
fastest.j@ncvc.go.jp

FASTEST

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 NCVC FASTEST office fastest.j@ncvc.go.jpand NCVC Central Pharmacy fastest.jpharm@ncvc.go.jp
- US Pharmacopeia (USP) rounding rules do apply for the temperature excursion (i.e., 0.5 °C is rounded up to 1°C and 30.4°C is rounded down to 30°F). Both examples are not a reportable excursion.
- Any temperature excursion affecting FASTEST study drug kits must be reported immediately, but at least within 48 hours of occurrence

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:

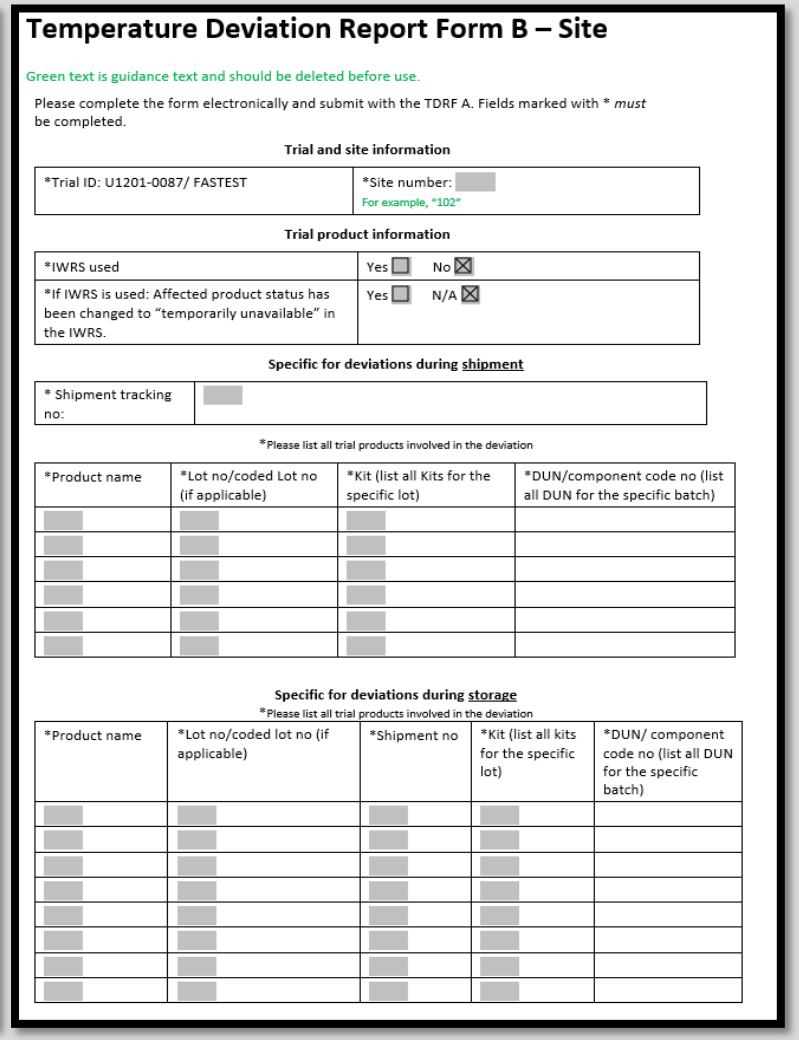
Additional information: Only if relevant to the case evaluation, for example arrival time of the products if the temperature deviation is due to data logger not stopped upon arrival

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)

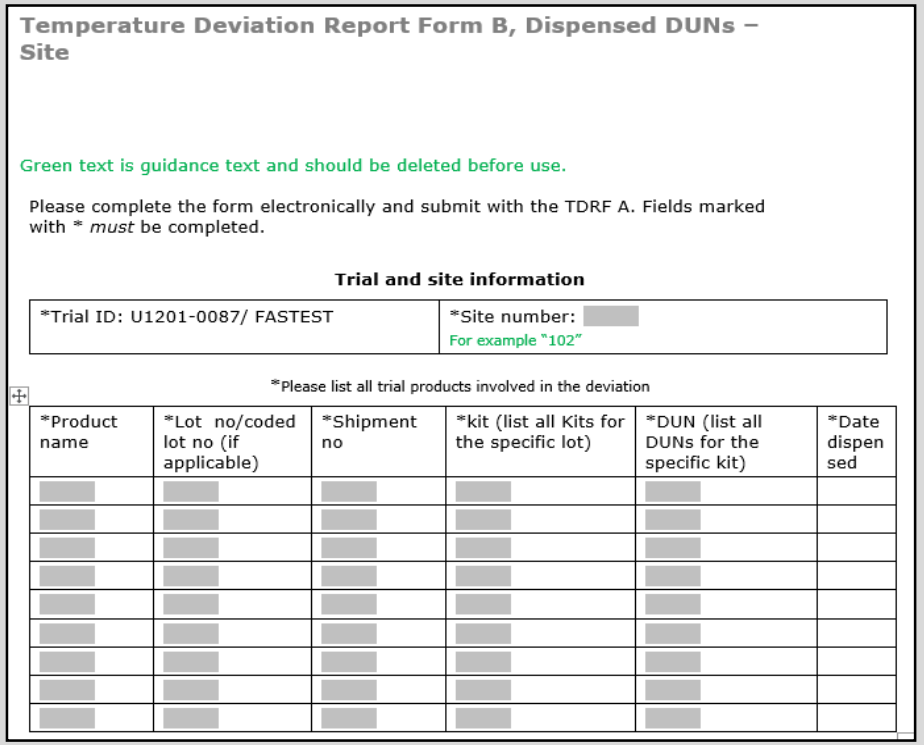
Specific for deviations during storage

*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

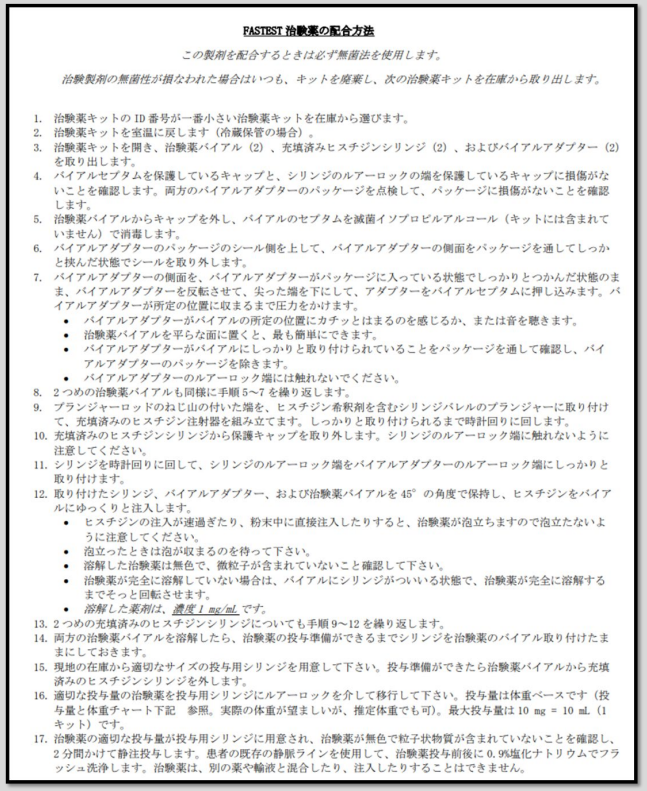
- The Temperature Excursion Report Form (TERF) - available in WebDCU™ Toolbox>Project Documents – submit for both storage and in-transit excursions

What’s inside the FASTEST kit?

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

FASTEST

Kit Component Boxes: Dosing/compounding card



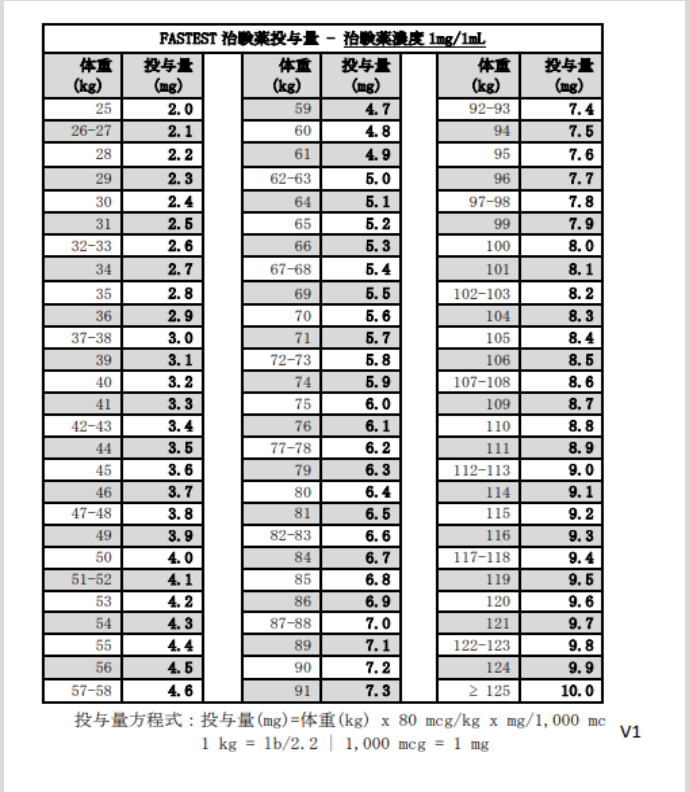
FASTEST 治験薬の配合方法

この製剤を配合するときは必ず無菌法を使用します。

治験製剤の無菌性が損なわれた場合はいつも、キットを廃棄し、次の治験薬キットを在庫から取り出します。

1. 治験薬キットの ID 番号が一番小さい治験薬キットを在庫から選びます。
2. 治験薬キットを室温に戻します（冷蔵保管の場合）。
3. 治験薬キットを開き、治験薬バイアル（2）、充填済みヒスチジンシリンジ（2）、およびバイアルアダプター（2）を取り出します。
4. バイアルセプタムを保護しているキャップと、シリンジのルアーロックの端を保護しているキャップに損傷がないことを確認します。両方のバイアルアダプターのパッケージを点検して、パッケージに損傷がないことを確認します。
5. 治験薬バイアルからキャップを外し、バイアルのセプタムを滅菌イソプロピルアルコール（キットには含まれていません）で消毒します。
6. バイアルアダプターのパッケージのシール側を上して、バイアルアダプターの側面をパッケージを通してしっかと挟んだ状態でシールを取り外します。
7. バイアルアダプターの側面を、バイアルアダプターがパッケージに入っている状態でしっかりとつかんだ状態のまま、バイアルアダプターを反転させて、尖った端を下にして、アダプターをバイアルセプタムに押し込みます。バイアルアダプターが所定の位置に収まるまで圧力をかけます。
   - バイアルアダプターがバイアルの所定の位置にカチッとはまるのを感じるか、または音を聴きます。
   - 治験薬バイアルを平らな面に置くと、最も簡単にできます。
   - バイアルアダプターがバイアルにしっかりと取り付けられていることをパッケージを通して確認し、バイアルアダプターのパッケージを除きます。
   - バイアルアダプターのルアーロック端には触れないでください。
8. 2 つめの治験薬バイアルも同様に手順 5～7 を繰り返します。
9. プランジャーロッドのねじ山の付いた端を、ヒスチジン希釈剤を含むシリンジバレルのプランジャーに取り付けて、充填済みのヒスチジン注射器を組み立てます。しっかりと取り付けられるまで時計回りに回します。
10. 充填済みのヒスチジンシリンジから保護キャップを取り外します。シリンジのルアーロック端に触れないように注意してください。
11. シリンジを時計回りに回して、シリンジのルアーロック端をバイアルアダプターのルアーロック端にしっかりと取り付けます。
12. 取り付けたシリンジ、バイアルアダプター、および治験薬バイアルを 45° の角度で保持し、ヒスチジンをバイアルにゆっくりと注入します。
    - ヒスチジンの注入が速過ぎたり、粉末中に直接注入したりすると、治験薬が泡立ちますので泡立たないように注意してください。
    - 泡立ったときは泡が収まるのを待って下さい。
    - 溶解した治験薬は無色で、微粒子が含まれていないこと確認して下さい。
    - 治験薬が完全に溶解していない場合は、バイアルにシリンジがついいる状態で、治験薬が完全に溶解するまでそっと回転させます。
    - *溶解した薬剤は、濃度 1 mg/mL です。*
13. 2 つめの充填済みのヒスチジンシリンジについても手順 9～12 を繰り返します。
14. 両方の治験薬バイアルを溶解したら、治験薬の投与準備ができるまでシリンジを治験薬のバイアル取り付けたままにしておきます。
15. 現地の在庫から適切なサイズの投与用シリンジを用意して下さい。投与準備ができたら治験薬バイアルから充填済みのヒスチジンシリンジを外します。
16. 適切な投与量の治験薬を投与用シリンジにルアーロックを介して移行して下さい。投与量は体重ベースです（投与量と体重チャート下記　参照。実際の体重が望ましいが、推定体重でも可）。最大投与量は 10 mg = 10 mL（1 キット）です。
17. 治験薬の適切な投与量が投与用シリンジに用意され、治験薬が無色で粒子状物質が含まれていないことを確認し、2 分間かけて静注投与します。患者の既存の静脈ラインを使用して、治験薬投与前後に 0.9%塩化ナトリウムでフラッシュ洗浄します。治験薬は、別の薬や輸液と混合したり、注入したりすることはできません。

Compounding instruction (Japan)



FASTEST 治験薬投与量 – 治験薬濃度 1mg/1mL

体重 (kg)	投与量 (mg)	体重 (kg)	投与量 (mg)	体重 (kg)	投与量 (mg)
25	2.0	59	4.7	92–93	7.4
26–27	2.1	60	4.8	94	7.5
28	2.2	61	4.9	95	7.6
29	2.3	62–63	5.0	96	7.7
30	2.4	64	5.1	97–98	7.8
31	2.5	65	5.2	99	7.9
32–33	2.6	66	5.3	100	8.0
34	2.7	67–68	5.4	101	8.1
35	2.8	69	5.5	102–103	8.2
36	2.9	70	5.6	104	8.3
37–38	3.0	71	5.7	105	8.4
39	3.1	72–73	5.8	106	8.5
40	3.2	74	5.9	107–108	8.6
41	3.3	75	6.0	109	8.7
42–43	3.4	76	6.1	110	8.8
44	3.5	77–78	6.2	111	8.9
45	3.6	79	6.3	112–113	9.0
46	3.7	80	6.4	114	9.1
47–48	3.8	81	6.5	115	9.2
49	3.9	82–83	6.6	116	9.3
50	4.0	84	6.7	117–118	9.4
51–52	4.1	85	6.8	119	9.5
53	4.2	86	6.9	120	9.6
54	4.3	87–88	7.0	121	9.7
55	4.4	89	7.1	122–123	9.8
56	4.5	90	7.2	124	9.9
57–58	4.6	91	7.3	≥ 125	10.0

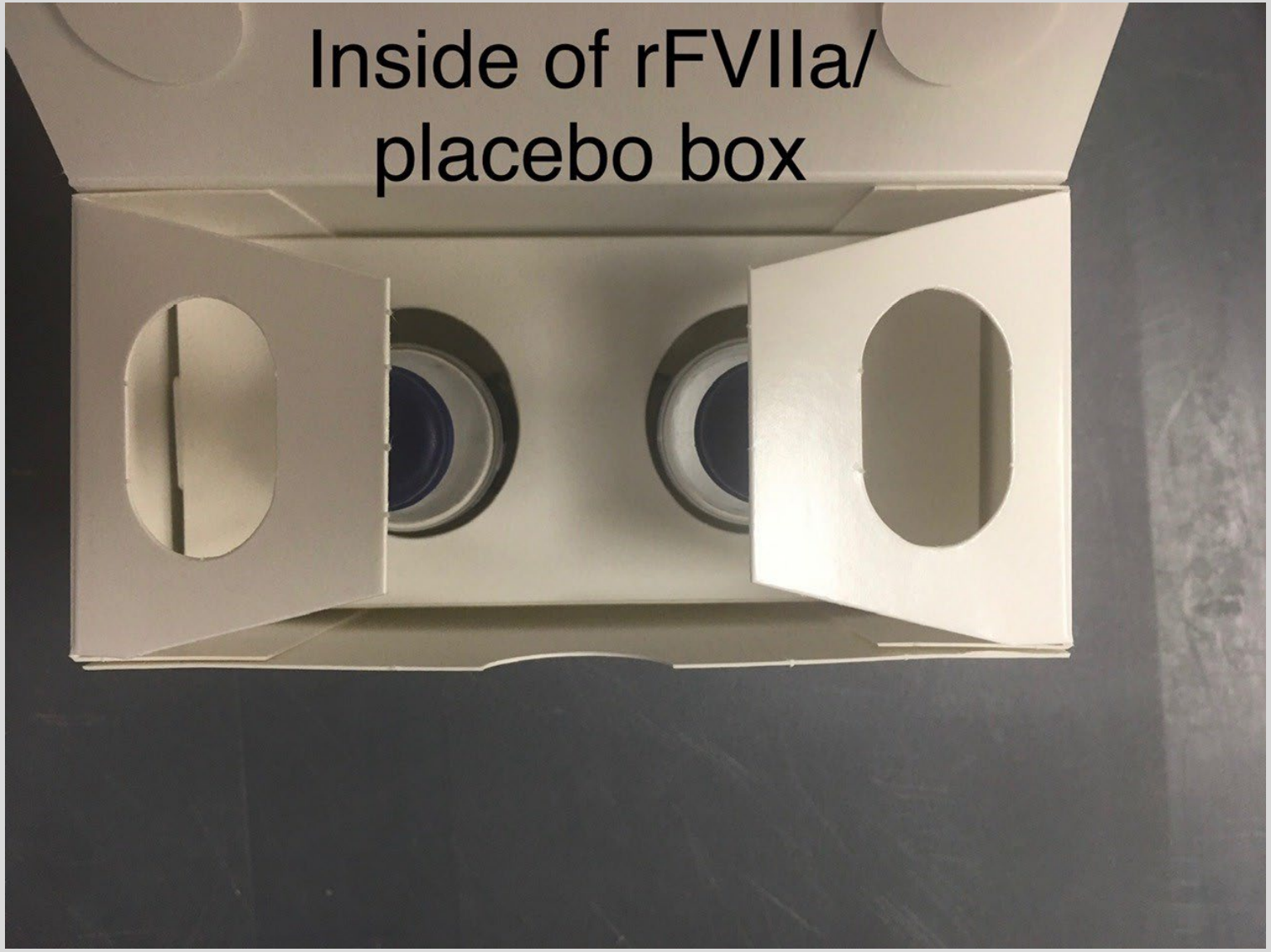
投与量方程式：投与量(mg)=体重(kg) x 80 mcg/kg x mg/1,000 mc
1 kg = 1b/2.2 | 1,000 mcg = 1 mg

V1

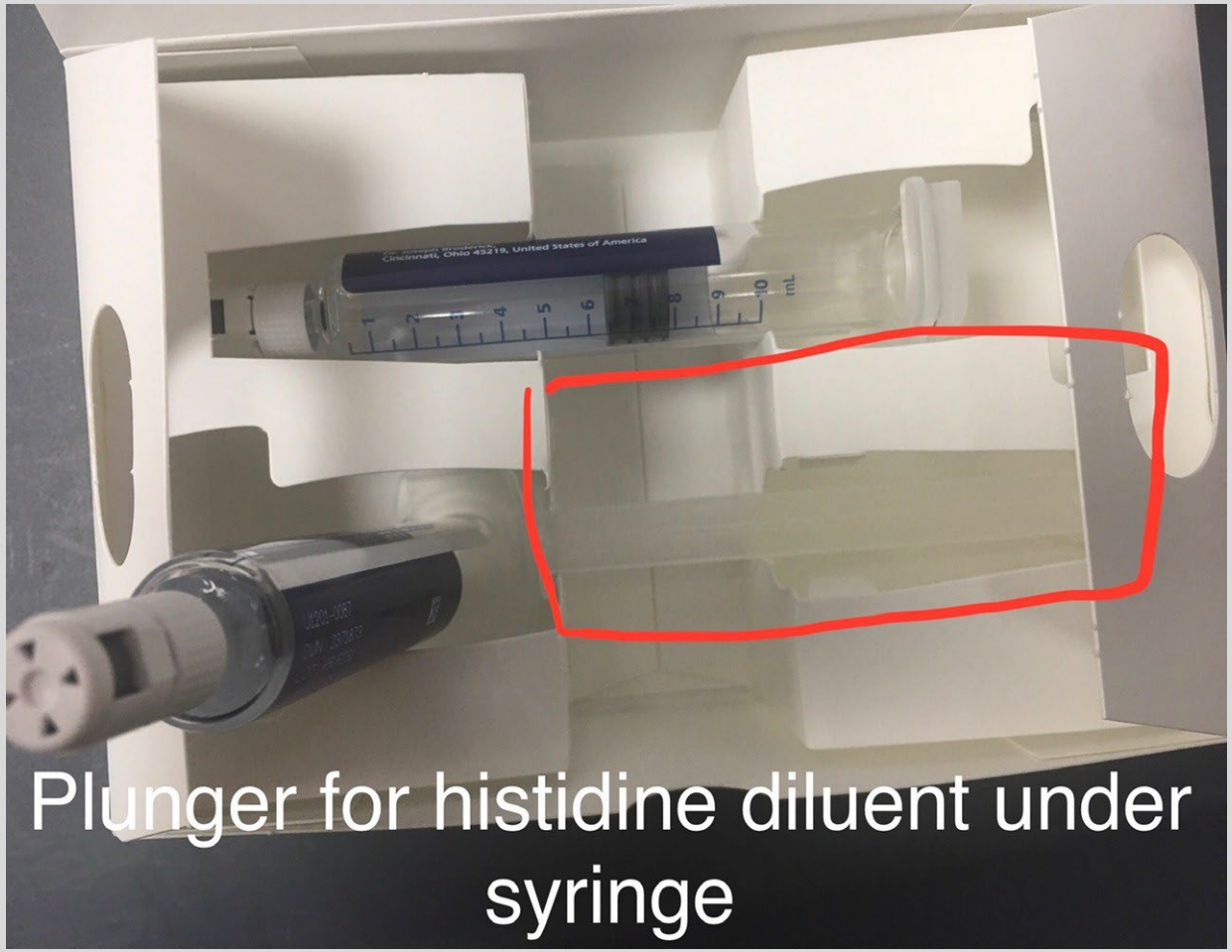
Dosing chart (Japan version)

- **Card in Japan language added to each kit**

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 logs serve 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 NCVC Central 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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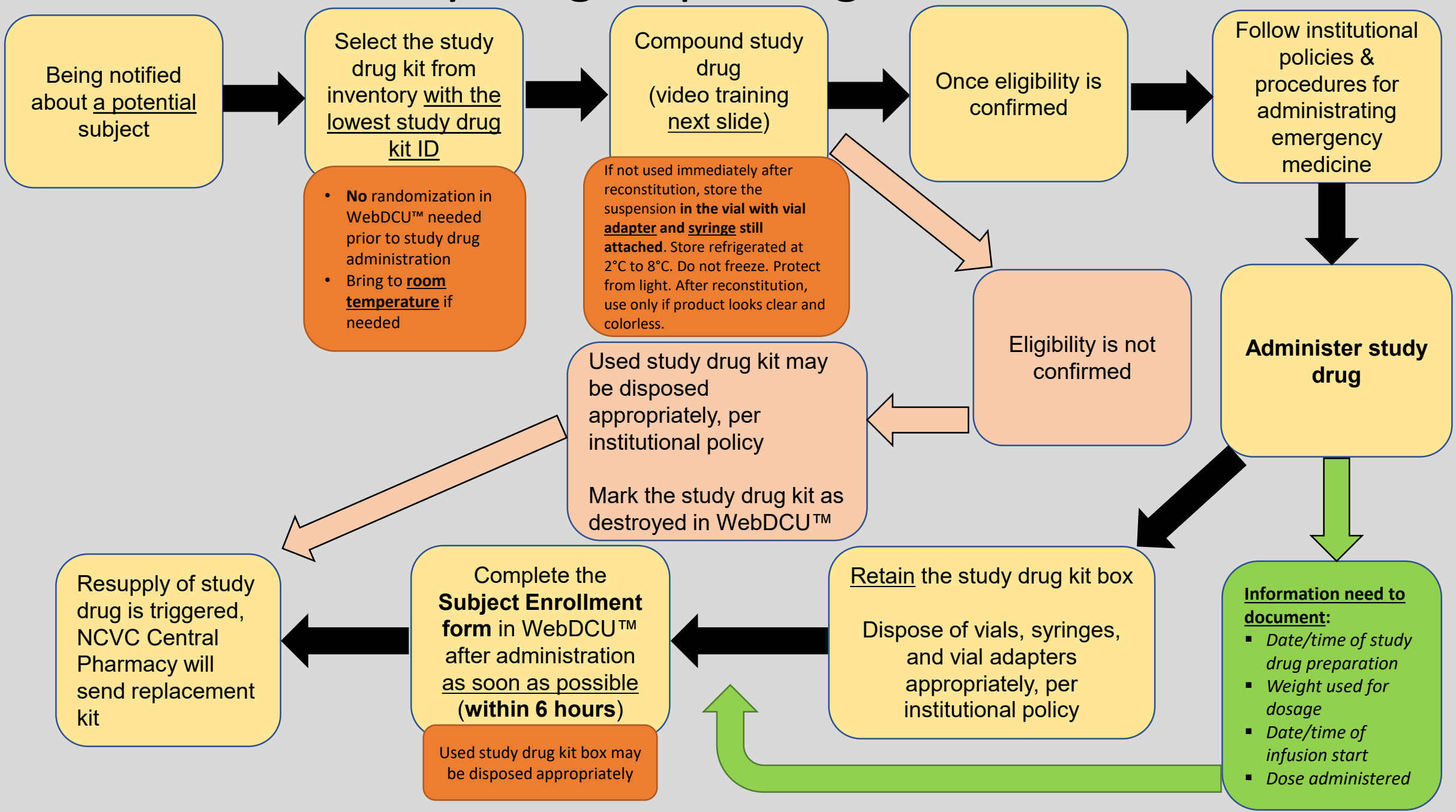
Chain of Custody

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

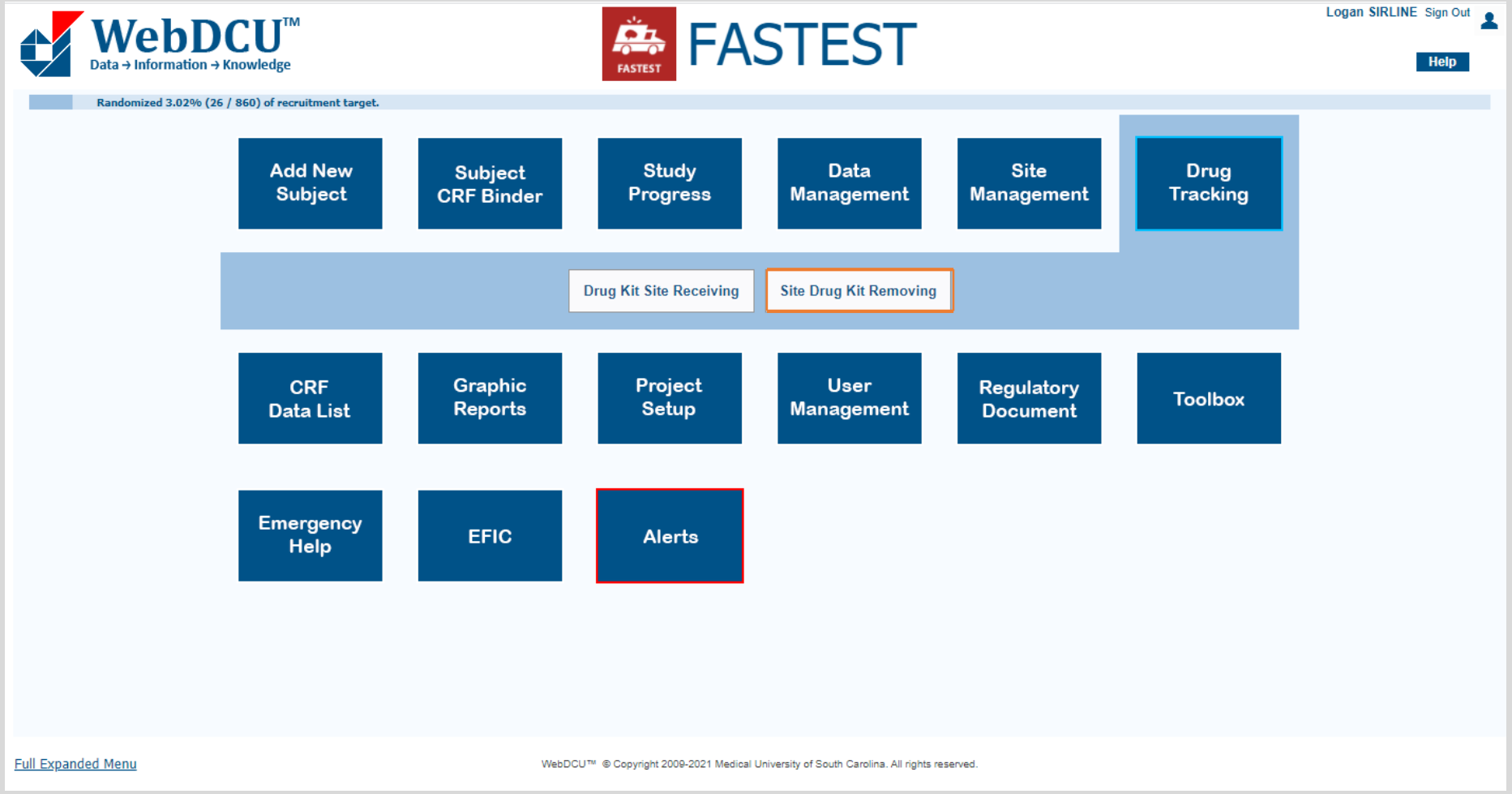
Instructions: *Any exchange of FASTEST Kits should be documented on this form*

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 Kit Removing



Compounding Video

Please review and refer to the pharmacy compounding video for visual demonstration. Find the video located on the WebDCU training campus, link below, under project specific training, the FASTEST Project:

https://dcu.musc.edu/campus/

IMPORTANT

- The pre-filled 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 NCVC Central Pharmacy when:
- Site released to receive study drug
- Subjects are randomized (complete Subject Enrollment form in WebDCU™ within **6 hours** of drug administration)
- Study drug is damaged/expired
  - Drug request will be sent to the NCVC Central Pharmacy prior to kit expiration

Study Drug Kit Expiration

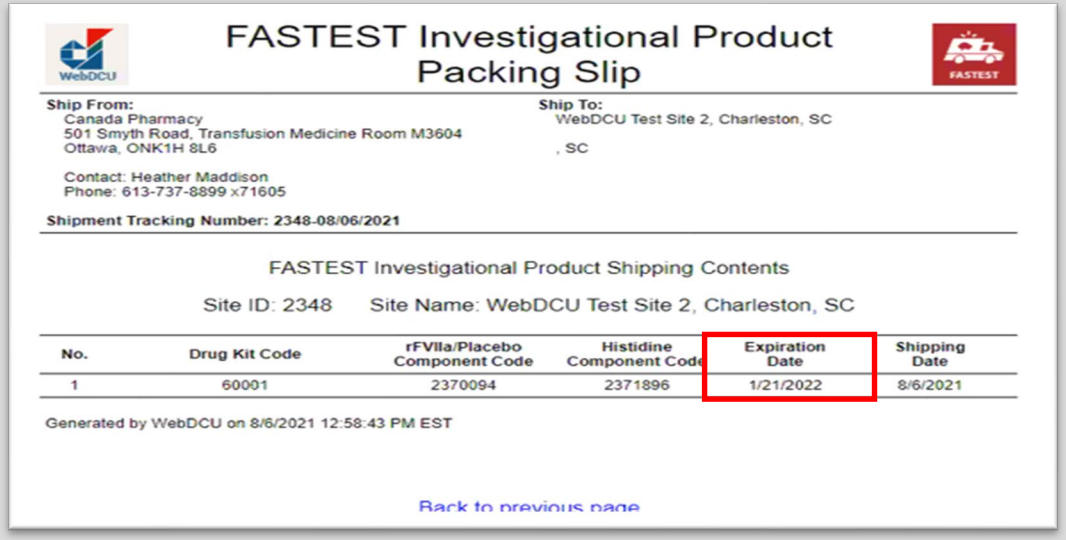
Study drug kit expiration dates are available in 3 locations:

- Study drug kit labels
- FASTEST study drug packing slip
- WebDCU™ (Drug Tracking Tab>Site Drug Kit Removing)

CPSs will receive emails from WebDCU™ and the NCVC 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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FASTEST

Study Drug Destruction & Return

CPSs should follow their institutional policy regarding drug destruction protocol

The Central Pharmacy can accept returns for destruction if a CPS's institutional policy requires returning the damaged or expired drug kits

Follow the steps below to return study drug to the NCVC 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 NCVC 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 NCVC Central Pharmacy via email

Temperature monitoring is NOT required for returns

Subject identifiers must be removed from returns

Study Drug Destruction & Return form

FASTEST 試験薬廃棄手順

1. 使用済み試験薬(空バイアル、残液あり)
   ・投与終了後、試験実施施設の薬局に返却する。
   ・試験実施施設の試験薬管理担当者による確認後、その施設の廃棄に関するルールに従って処分する。
   ・キットボックス(外箱)ラベルに表示されているキット ID を WebDCU に入力し、外箱を廃棄する。

   日本における一般医薬品廃棄物の物の分離
   バイアル：ガラス、注射器：プラスチック、外箱：紙くず

2. 未使用の試験薬
   (試験薬の有効期限が切れた時、試験が中止されたとき、試験が終了したとき)
   ・試験実施施設の試験薬管理担当者は日本の中央薬局に返却を依頼する(付録 G)。
   ・中央薬局が承認後、試験管理担当者は試験薬を中央薬局に返送する。

3. 試験薬の破損(調製失敗、落下破損)
   ・試験実施施設の試験薬管理担当は中央薬局に連絡する。
   ・中央薬局が承認後、試験実施施設のルールに従って試験薬を廃棄する。
   ・キットボックス(外箱)ラベルに表示されているキット ID を WebDCU に入力し、外箱を廃棄する。

   日本における一般医薬品廃棄物の物の分離
   バイアル：ガラス、注射器：プラスチック、外箱：紙くず

試験実施施設名称
試験実施施設 PI の印刷名
試験実施施設 PI の署名
試験実施施設PI署名の日付

年　月　日

試験薬返却書

（返却・紛失・破棄報告書）

FASTEST 研究代表医師
国立循環器病研究センター　副院長
豊田　一則　殿

研究実施医療機関名：（　　）

研究責任（分担）医師：（　電子署名　）

試験薬管理者：（　電子署名　）

下記の通り、試験薬の返却・紛失・破棄を報告します。

記

試験名：FATEST 試験

返却・紛失・廃棄薬剤

Study Drug Kit ID	試験薬製造番号（溶解液除く）	数量	返却・紛失・廃棄の別
			返却 ・ 紛失 ・ 廃棄
			返却 ・ 紛失 ・ 廃棄
			返却 ・ 紛失 ・ 廃棄
			返却 ・ 紛失 ・ 廃棄
紛失／廃棄の場合は理由を記載		理由：	

以上

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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 …

- NCVC Central Pharmacy to resupply you with study drug as **FAST** as they can.

Questions?

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

Toolbox>Project Documents