U.S. Army Medical Research and Materiel Command (USAMRMC)
Office of Regulated Activities (ORA)
Data Management Branch

Mock Electronic Case Report Form (eCRF) Book

CRF Version: 1.1 (August 30, 2018)

FINAL

Sponsor: The Surgeon General, Department of the Army (TSG-DA)

Project #: S-18-03; EUA FDP

Project Title: "EUA: *Pathogen-Reduced Leukocyte-Depleted Freeze-Dried Plasma (FDP)"*

EUA Product: Pathogen Reduced Leukocyte-Depleted Freeze Dried Plasma (Centre de Transfusion Sanguine des Armées)

EUA Authorization Letter Version: July 9, 2018

Prepared By: Brianna Johnson, USAMMDA Data Manager

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APPROVAL SIGNATURES

We approve the contents and format of this document for the above referenced project and hereby release it as the data entry screen specifications. The data entry screens in the study database shall be designed and set up according to this mock eCRF book.

Version Type	Version Date	Remark
1.0	July 27, 2018	
1.1	August 30, 2018	Updated "Subject Number" question text to "Recipient Number" to fix issue with database reporting.
Role	**Name (First Last, Title)**	**Signature and Date**
Data Manager/ designee	Brianna Johnson	JOHNSON.BRIANNA.NICHOLE.1542351310 Digitally signed by JOHNSON.BRIANNA.NICHOLE.1542351310 Date: 2018.08.30 11:42:14 -04'00'
Data Manager/ designee	Paileen Mongelli	MONGELLI.PAILEEN.BUNTA.1382698467 Digitally signed by MONGELLI.PAILEEN.BUNTA.1382698467 Date: 2018.09.05 07:53:16 -04'00'
Chief, Data Management Branch/ designee	Dixion Rwakasyaguri	RWAKASYAGURI.DIXION.TUMURAM.1263894711 Digitally signed by RWAKASYAGURI.DIXION.TUMURAM.1263894711 Date: 2018.09.05 13:35:57 -04'00'
Clinical Research Associate/ designee	Anna Marie Seale	SEALE.ANNA.MARIE F.1250249620 Digitally signed by SEALE.ANNA.MARIE F.1250249620 Date: 2018.09.05 10:00:10 -04'00'
Product Manager/ designee	LTC Michael Yapp	YAPP.MICHAEL.ELSWORTH.1186085970 Digitally signed by YAPP.MICHAEL.ELSWORTH.1186085970 Date: 2018.09.05 12:54:34 -04'00'

ECRF PAGE MATRIX

Visit eCRF Page	Required
System Registration	
1. System Subject Registration	X
System Enrollment	
1. System Subject Enrollment	X
EUA Participation	
1. Subject Management	X
2. Start of Participation	X
3. Treatment Administration	X
4. End of Participation	X

UNIQUE ECRF PAGES

Domain: System Registration – ZS (System Requirement)		
Visit:	SYSTEM REGISTRATION	
Page:	SYSTEM SUBJECT REGISTRATION	
Section:	SUBJECT INITIALS	
Line #	**Question**	**Response**
1.	Recipient Initials (derived)	- - - Defaulted with dashes, no actual values collected.

Domain: System Enrollment – ZE (System Requirement)		
Visit:	SYSTEM ENROLLMENT	
Page:	SYSTEM SUBJECT ENROLLMENT	
Section:	SUBJECT NUMBER ASSIGNMENT	
Line #	**Question**	**Response**
1.	Recipient ID Code (3 digits)	___ ___ ___ # # # *Manual entry by Site where:* • *### represents a sequential 3 digit number based on the order of enrollment into the project at Site level, starting with 001.*
2.	Recipient Number	SITEID -___ ___ ___ # # # • *Derived from the values of Site ID + Recipient ID Code (3 digits) to promote value uniqueness across study.* • *Site ID examples are USASOC, MARSOC, AFSOC, NSW*

Domain: Subject Management – ZM		
Visit:	EUA PARTICIPATION	
Page:	SUBJECT MANAGEMENT	
Section:	SUBJECT NUMBER UPDATE	
Line #	**Question**	**Response**
1.	Recipient Number	SITEID -___ ___ ___ # # # *Derived from SYSTEM SUBJECT ENROLLMENT page with edit mode*
2.	Recipient Deletion Flag (Equivalent to "DELETION"; to be excluded from Data Entry, SDV, Query, and Analysis, "D" suffix added to Recipient Number)	[ ] DELETION
3.	Recipient Deletion Reason	_____

Domain: Start of Participation – DS/DM (Project Defined)		
Visit:	EUA PARTICIPATION	
Page:	START OF PARTICIPATION	
Section:	ENROLLMENT	
Line #	**Question**	**Response**
1.	How did the recipient receive the information about the product under the EUA?	Check All That Apply: [ ] FM: Fact Sheet for U.S. Military [ ] FR: Fact Sheet for Recipients [ ] IC: IND Informed Consent [ ] U: Unknown [ ] O: Other, specify
2.	Other Information for Recipient	_____
3.	Recipient Informed Date (DD/MON/YYYY)	Dropdown(Calendar Pick): ___ ___ / ___ ___ ___ / ___ ___ ___ ___ D D M O N Y Y Y Y
Section:	DEMOGRAPHY INFORMATION	
Line #	**Question**	**Response**
4.	Date of Birth (DD/MON/YYYY)	Dropdown(Calendar Pick): ___ ___ / ___ ___ ___ / ___ ___ ___ ___ D D M O N Y Y Y Y
5.	Sex	Dropdown: [ ] F: Female [ ] M: Male
6.	Ethnicity	Dropdown: [ ] HL: Hispanic or Latino [ ] NHL: Not Hispanic or Latino [ ] UNK: Unknown
7.	Race	Dropdown: [ ] 1: White [ ] 2: Black or African American [ ] 3: American Indian or Alaska Native [ ] 4: Asian [ ] 5: Native Hawaiian or Other Pacific Islander [ ] 96: Unknown [ ] 99: Other or Multiple
8.	Other or Multiple Races *(If "Other or Multiple" is selected, specify other/multiple race)*	_____

Domain: Exposure – EX (Interventions)		
Visit:	EUA PARTICIPATION	
Page:	TREATMENT ADMINISTRATION	[ADD ENTRY
Section:	ADMINISTRATION COMPLETION	
Line #	**Question**	**Response**
1.	Dose Entry Number	#
2.	Dose Administered?	Dropdown: [ ] Y: Yes [ ] N: No
3.	Product Name	Dropdown: [ ] FF: French FDP from France Collection [ ] FS: French FDP from US Collection [ ] CA: USP-Grade Calcium Solution
4.	Treatment Indication	Dropdown: [ ] C: Coagulopathy [ ] H: Hemorrhage [ ] O: Other Specify
5.	Specify Other Treatment Indication	_____
6.	Administration Date (DD/MON/YYYY)	Dropdown(Calendar Pick): ___ ___/___ ___ ___/___ ___ ___ ___ D D M O N Y Y Y Y
7.	Administration Time (24 hr Clock)	Dropdown: ___ ___ : ___ ___ H H M M
8.	Actual Dose	_____
9.	Dose Unit	mL *Defaulted to "mL" for FF and FS but editable.
10.	Lot Number	_____
11.	Trace Number	_____

Domain: Disposition – DS (Events)		
Visit:	EUA PARTICIPATION	
Page:	DISPOSITION: END OF PARTICIPATION	
Section:	FINAL PARTICIPATION STATUS	
Line #	**Question**	**Response**
1.	Recipient Final Participation Status (30 days following treatment)	Dropdown: [ ] 101: Completed [ ] 301: Withdrawal by subject [ ] 302: Physician decision, specify detail [ ] 303: Lost to follow-up [ ] 304: Adverse event, specify AE Line No and/or detail [ ] 305: Protocol deviation, specify detail [ ] 308: Site terminated by sponsor [ ] 309: Study terminated by sponsor [ ] 318: Death [ ] 999: Other, specify detail
2.	Specify Status Detail	_____
3.	Recipient Final Participation Date (DD/MON/YYYY)	Dropdown(Calendar Pick): ___ ___ / ___ ___ ___ / ___ ___ ___ ___ D D M O N Y Y Y Y
Section:	TREATMENT OUTCOME	
Line #	**Question**	**Response**
4.	Recipient Survival Status (Until transfer of care)	Dropdown: [ ] S: Survived [ ] D: Deceased [ ] U: Unknown
5.	Recipient Survival Status (30 days following treatment)	Dropdown: [ ] S: Survived [ ] D: Deceased [ ] U: Unknown
6.	Study Completion Status	xxx *Derived based on Subject Status to meet system's requirements*
7.	Drop-out Reason	xxx *Derived based on Subject Status to meet system's requirements*

REVISION HISTORY

Mock eCRF Revision History

Line #	Revision Date	eCRF Book Version *(Prior to Change)*	Page	Item	Change Description	Reason for Change
1.	7/25/2018	7/16/2018 (Draft v0.1)	Adverse Event	All	Removed the page.	• Per the discussion and its conclusion in the EUA Working Group meeting on 7/18/2018, AEs and all medication errors associated with the use of the product will not be captured in the eCRF database as they'll be reported to FDA directly via MedWatch reports and the sites are to send a copy of the completed MedWatch reports to PSSB. As a result, AE and Protocol Deviations pages are removed from the Mock eCRF Book.
2.	7/25/2018	7/16/2018 (Draft v0.1)	Protocol Deviations	All	Removed the page.	• Per the discussion and its conclusion in the EUA Working Group meeting on 7/18/2018, AEs and all medication errors associated with the use of the product will not be captured in the eCRF database as they'll be reported to FDA directly via MedWatch reports and the sites are to send a copy of the completed MedWatch reports to PSSB. As a result, AE and Protocol Deviations pages are removed from the Mock eCRF Book.

Mock eCRF Revision History

Line #	Revision Date	eCRF Book Version *(Prior to Change)*	Page	Item	Change Description	Reason for Change
3.	7/26/2018	7/26/2018 (Draft v0.2)	All	All	Updated or removed the word 'protocol' when referring to the EUA.	• The Product Manager, Danny Hassan, recommended the word 'protocol' should not be used after his review on 7/26/2018 as the word has specific meaning in regulatory terms. Please note, the codelist option '305: Protocol deviation, specify detail' will not be removed so that deviations from procedures can be reported, if needed.
4.	7/27/2018	7/27/2018 (Draft v0.3)	All	All	Finalized and changed to Final version 1.0.	• To finalize the draft version of the Mock eCRF for use in eCRF Database development.
5.	8/30/2018	7/27/2018 (Final v1.0)	Subject Management	All		• "Subject Number" is a reserved system variable for Inform and cannot be used as a variable for a protocol specific database; therefore, the question text was updated to "Recipient Number". The other questions on the form were updated to refer to "recipient" for consistency.
6.	8/30/2018	7/27/2018 (Final v1.0)	System Subject Registration	Subject Initials	Question text updated to "Recipient Initials".	• Question text updated to refer to "recipient" for consistency with the Subject Management form.
7.	8/30/2018	7/27/2018 (Final v1.0)	System Subject Enrollment	Patient ID Code	Question text updated to "Recipient ID Code".	• Question text updated to refer to "recipient" for consistency with the Subject Management form.