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Purpose

The purpose of this document is to provide detailed instructions for the steps required for a site to become regulatory compliant for the P-ICECAP study. The process for user management and regulatory document management within the WebDCU system are

covered. In addition, detailed instructions are provided for completing the information required by the Clinical Coordinating Center (CCC) to complete a site application to the Central IRB (Advarra), on each site's behalf.

Abbreviations

PI = Principal Investigator
Sub-I = Sub- or Co-Investigator
PSC = Primary Study Coordinator
SSC = Secondary Study Coordinator
RDC = Regulatory Documents Coordinator

User Management

UM FRIEND ACCOUNT

Access to all the SIREN clinical trial Education and Training pages, including Toolboxes and FAQs, require a UM Friend Account LoginID and Password. For information about UM Friend Accounts, click here. To create a UM Friend Account go to https://friend.weblogin.umich.edu/friend/.

Completing the eDOA (electronic Delegation of Authority)

In WebDCU under the User Management tab

In accordance with FDA's regulations, investigators are required to commit to personally conduct or supervise the investigation (for drug and biologic studies under 21 CFR 312.53(c)) or to supervise all testing (for medical device studies under 21 CFR 812.43(c)).

FDA's regulations do not require an eDOA. This log, however, is among the documents listed in the ICH E6 Good Clinical Practice (GCP) document which is official FDA guidance. It states in section 4.1.5:
4.1.5 The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

Another FDA guidance document titled, "Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects" discusses a clinical investigator's responsibilities when delegating study tasks.

eDOA log parameters Table

The minimum study personnel that must be selected for each responsibility on the eDOA for P-ICECAP. More than the minimum is preferred.

RESPONSIBILITY	ROLE ASSIGNMENT (at minimum)
Overall responsibility for the trial (A)	PI
Obtain informed consent (B)	PI, PSC, SSC (24/7 coverage needed)
Determine eligibility (C)	PI or any other team member determining eligibility (24/7 availability for consulting)
Perform randomization (D)	PSC, SSC (24/7 coverage needed)
Complete Case Report forms (E)	PSC, SSC, PI
Report adverse events (F)	PI, PSC, SSC
Maintain essential regulatory documents (G)	PSC, RDC
Internal SIREN Hub/Spoke Verification (SA)	N/A
Ongoing Clinical Team Training (SB)	PSC, PI
Subject tracking/Follow up (SC)	PSC

Regulatory Documents

People Regulatory Document Collection

REGULATORY REQUIREMENTS			APPROVAL PARAMETERS			
	Person		Effective Date	Expiration Date	Waived	

Document	**Role**	**Document Type**	**dd/mmm/yyyy**	**dd/mmm/yyyy**	**Y/N**	**Instructions for WebDCU™** Please upload all documents in **pdf** format to WebDCU™.
CV	*PI, Sub-I, PSC, SSC, RDC	People	Use date within document	2 years from source date	No	Required for all site personnel listed on the DOA log and any other personnel who are directly involved in the study. Document must have a date. *PI's CV must include previous clinical trial/human subjects research experience. Provide source in a pdf attachment.
HSP Certification	PI, Sub-I, PSC, SSC, RDC	People	Use source (date certification completed)	Site-specific	No	Please follow the local institutional policies for completion and ongoing maintenance of HSP training. If your institution requires re-training and provides an expiration date for the certification, enter this date into WebDCU™ and you will receive a notification as that date nears. Please provide the corresponding HSP Certification for each study team member in a pdf attachment. ***Sites outside of the US**: Upload completed HSP statement of training for each team member. Must be signed by local PI. No expiration date needed.
Investigator Agreement	Principal Investigator	People	Use source (date of signature)	End of Trial (leave blank)	No	This form must be reviewed, signed and dated by the Principal Investigator. The form can also be found on the P-ICECAP Getting Started page. ***Sites outside of the US**: Local PI must sign

GCP Training	PI, Sub-I, PSC, SSC, RDC, and other Data Collection/ Entry/Management Personnel	People	Use source (date certification completed)	Use the date on source or 3 years from effective date, whichever is earlier	No	The National Institutes of Health (NIH) policy (NOT-OD-16-148) requires investigators, clinical trial staff including study coordinators and data managers involved in the conduct, oversight, or management of NIH-funded clinical trials to be trained in Good Clinical Practice (GCP). This training requirement is in addition to (and does not replace) the basic required human subjects' protection training (e.g., CITI human subjects modules). The policy notes that GCP training should be refreshed at least every three years. Follow your institutional policy for GCP training. Provide source in a pdf attachment. ***Sites outside of the US:** Upload GCP training certificate for each team member.
Medical License	PI, Sub-I,	People	Use source "issuance date," if no date, use date uploaded	Required – use source	Yes	Upload a copy of the current medical or professional license into WebDCU™. Copies of online verifications are valid, unless a disclaimer is noted on the license. Provide source in a pdf attachment. ***Sites outside of the US:** Upload a copy of the current medical or professional license into WebDCU™.
Protocol Training	PI, Sub-I, PSC, SSC	People	Use date certification was completed	NA - leave blank	Yes*	Training is available on the P-ICECAP website's Education and Training page. Study team members listed on the eDOA are required to complete the protocol training. The training has three requirements. (1) Review the protocol and clinical standardization guidelines; (2) Watch the "Protocol Introduction and Rationale", "Protocol Review" **AND** "P-ICECAP Game" videos; and (3) Complete the attestation form located in WebDCU.
Regulatory Document	RDC, Team members maintaining	People	Use date on attestation	NA – leave blank	No	Regulatory document management training is available in the P-ICECAP Education and Training (Education and Training – SIREN Network). Once the training

Management Training	regulatory compliance					is completed, an attestation will need to be completed using the link provided on the website. Upload the certificate into WebDCU™. Access will then be granted for new user accounts. Provide source in a pdf attachment.
Data Training	Complete Case Report form, Perform randomization,	People	Use date on attestation	NA – leave blank	No	CRF data training will be available on the P-ICECAP website under the Education and Training (Education and Training – SIREN Network) tab. Once the training is completed, an attestation will need to be completed using the link provided on the website. Upload document as PDF into WebDCU database. P-ICECAP data entry accounts cannot be activated until the P-ICECAP Data Training Certificate is uploaded to WebDCU™. Provide source in a pdf attachment.

Site Regulatory Document Collection

REGULATORY REQUIREMENTS				APPROVAL PARAMETERS	
Document	**Document Type**	**Effective Date dd/mmm/yyyy**	**Expiration Date dd/mmm/yyyy**	**Waived Y/N**	**Instructions for WebDCU™** Please upload all documents in **pdf** format to WebDCU™
Federal Wide Assurance*	site	Use source approval date, if a date is not provided, use date uploaded	Required – use source expiration date	No	Provide documentation of a Federal wide Assurance (FWA). Upload a copy of the FWA, pulled from the OHRP website, to WebDCU™. Office for Human Research Protections Database (nih.gov. Find your institution using either the basic or advanced search. Provide source in a pdf attachment. *** Sites outside the US**: please go to https://ohrp.cit.nih.gov/search/search.aspx, find your institution under IORG search, and upload a PDF of your institution.
Attestation of Local Education & Training	site	Use signature date	NA - leave blank	No	Each PI is required to sign an attestation form that he/she accepts responsibility of the protocol and training responsibilities for all personnel who might be involved with the treatment or assessment of P-ICECAP subjects at their site. Attestation of Local Education & Training Form. PICECAP Website under Getting Started. Getting Started | SIREN *** Sites outside the US**: Local Site PI must sign

Ceding Request to Local IRB*	site	Use Source	NA - leave blank	No	Submission documentation (screenshot, email, etc.) that the local IRB or the site local Human Research Protection office has been sent an administrative review (ceding request) application for the P-ICECAP study. ***Sites outside the US**: Upload completed template "Ceding Request to Local IRB" which states local governance application date and consent versions.
Ceding Acknowledgment from Local IRB*	site	Use source	NA - leave blank	No	Local IRB or Human Research Protection office acknowledgement or notice of completed administrative review for P-ICECAP. Reach out to your local IRB/HRP office for guidance about how they need to be notified about P-ICECAP. While IRB board review and approval of P-ICECAP is being conducted through the SIREN cIRB, all other institutional oversight and compliance to conduct research locally will still be managed locally. Provide your IRB/HRP office P-ICECAP acknowledgment documentation in WebDCU for this record requirement. ***Sites outside the US** should upload their site Local Governance Approval approval here.
PI Attestation of Retraining	site	Use signature date	NA - leave blank	No	Site PI is required to sign the attestation form after the site team has completed all retraining tasks, per study requirements and SIREN SOP. ***Sites outside the US:** Local PI to sign attestation form after site team has completed all retraining tasks per study requirements and SOP.
HSP Requirements	site	Use date of upload	NA - leave blank	No	Provide within this entry the Human Subject Protection (HSP) training/certification requirements for research at your site as defined by your local research administration office. Upload documentation of local HSP training requirements as a pdf.

					NOTE: We need to see the interval (duration) of training/recertification (e.g. HSP training required every 3 years, etc.). ***Sites outside of the US:** Australia/New Zealand: upload template "HSP Requirements" which states that sites will adhere to National Statement on Ethical Conduct in Research, that sites are aware of NIH requirements surrounding human subject protections and that the content of the National Statement meets these requirements. Must be signed by Local PI.
Conflict of Interest	site	**Waive** or Use date of upload into WebDCU	NA- leave blank	Yes	If required (confirmed by the IRB application) use FDA COI Form 3455. A form and a plan to minimize bias must be completed for each study team member with a COI. Merge all files into 1 PDF and upload. If there are no Conflict of Interests (confirmed by the IRB application), this regulatory document can be waived. ***Sites outside the US:** If there are no Conflict of Interests, this regulatory document should be waived. If there is a COI, please answer questions in the form above.
Approved Consent to Continue Form	site	Use Ethics board approval date	No expiration date	No	For Australia and New Zealand and UK sites only
Site IRB Approval*	site	Populated by database by Advarra	Populated by database by Advarra ***Sites outside of the US:** use expiration date listed on Ethics approval	No	Documentation received from the ER-CIRB (Advarra) into the database. Initial and continuing renewal documentation from Advarra will be dropped into the database under this record name. **No US site action is required.**

					***Sites outside the US: Lead site** should upload the Human research Ethics Committee/ HRA Study approval. Documentation should list all participating sites, have a clear approval date, and expiration date. Subsequent documentation of IRB approval should also reside here. Provide source in a pdf attachment.
Site IRB Approved Informed Consent Form*	site	Populated by database by Advarra (**OUS**: populated by Lead site)	No leave blank	No	Documentation received from the ER-CIRB (Advarra) into the database. **No US site action is required** ***Sites outside the US:** Provide the Local Governance approved Informed Consent Form with clear documentation of the dated approval. Prior to submitting to your Ethics Board, your Consent Form(s) must be approved by the sponsor; please forward to picecap-contact@umich.edu for review.

Site IRB Approved Informed Consent Form Non-English*	site	Populated by database by Advarra	No leave blank	No	**No US site action is required** ***Sites outside the US:** If a non-English consent is to be used, provide the Ethics Board approved Informed Consent Form with clear documentation of the approval date. Prior to submitting to your IRB, your Consent Form(s) must be approved by the sponsor; please forward to picecap-contact@umich.edu for review.
IRB Study Communications *	site	Populated by database by Advarra	NA - leave blank	Yes	IRB communication regarding study team member changes, UAP, SAE's, closing to enrollment, etc., will be completed by site personnel on a separate WebDCU data entry form and submitted to the cIRB by the CCC. For US Sites, Advarra's response will be dropped into this regulatory record. **No US site action is required** ***Sites outside the US:** Upload written acknowledgment/approval from the Ethics Board of adverse event reporting, closing enrollment, study materials, or any document previously approved by the Ethics Board. Provide source in a pdf attachment.

IRB Acknowledgment - Site Close-Out*	site	Populated by database by Advarra	NA - leave blank	No	IRB Closeout Notification will be sent through a centralized e-form available in WebDCU. Advarra's Close-out Acknowledgment (response) will be dropped in this regulatory record. ***Sites outside the US:** Upload pdf of Ethics Board site closure confirmation.
Site eConsent Link	Site	Use initial IRB ICF approval date	NA - leave blank		Upload a PDF document with the eConsent short link. Your short link is the URL to your site specific PICECAP study eConsent form. Short links begin with "https://bit.ly/picecap" followed by text indicating your institution. For example, the short link for the Akron site is https://bit.ly/picecapAkron When creating the PDF of the short link, make sure the text with the URL is also linked to the actual URL so clicking on the text in the PDF opens a browser and goes to the consent form. *Sites outside the United States (OUS) should waive this requirement.
Site eConsent Link - Non-English	Site	Use initial IRB ICF approval date	NA - leave blank		Upload a PDF document with the Non-English eConsent short link. Your short link is the URL to your site specific PICECAP study eConsent form. Short links begin with "https://bit.ly/picecap" followed by text indicating your institution followed by "Spanish". For example, the short link for the Iowa PICECAP site is https://bit.ly/picecapIowaSpanish When creating the PDF of the short link, make sure the text with the URL is also linked to the actual URL so clicking on the text in the PDF opens a browser and goes to the consent form. *Sites outside the United States (OUS) should waive this requirement.

Central IRB (CIRB) Tables (US Sites Only)

Please complete the cIRB forms (in blue) in this order. Completed forms allow the CCC to submit individual site IRB submissions to Advarra on sites' behalf:

Go to SIREN Database [pathway: WebDCU SIREN > Central IRB (tile) > Site Overview & Site Regulatory Inspection History (Forms)]

Step 1: Complete the **Site Overview** table. In Row 21 select "complete, Pending CCC Review". If the table is incomplete and needs to be modified before submitting, please select "Pending Site Completion" and work toward completing the table as soon as possible.

Step 2: Review the **Site Regulatory Inspection History** table. You must complete a new record for each *regulatory inspection* for the Investigator or your research location(s) that have occurred in the last 5 years for FDA, OHRP, Health Canada, & other regulatory agency. Click on the blue number of the row and 'Add New' ***If there are no violations, there is no need to create a record.**

Go to P-ICECAP Database [pathway: WebDCU PICECAP-> Central IRB (tile) > Initial Site Submission (Form)]

Step 3: Complete the **Initial Site Submission** table. Complete the form. Save the form as "pending" until it is finalized and ready to submit.

The cIRB forms in the SIREN database must be completed before this form can be considered complete and ready for CCC review.

CIRB Tables Detailed Instructions for US sites ONLY.

Step 1: SITE Overview (Form)

No.	Item Description	Answer choices	Expected/Allowed Response
1	Site	Drop down list	Site specific
2	Site type	Research dedicated facility Private/group practice Hospital or hospital affiliated	Site specific

		University of university affiliated Psychiatric institution	
3	Of other, specify	Text field	
4	How many years has research been conducted at this location?	Less than 1 year 1-3 years 3 or more years	Site specific
5	Select all emergency equipment/staff available at this location	Crash Cart Emergency drugs [i.e. Benadryl/Epinephrine Access to 911 In-house “code” Defibrillator Oxygen CPR Certified Staff Other: Example: Warming equipment	Site specific; Warming equipment should be available and is indicated by adding to ‘other’
6	Select all additional resources available that are unrelated to emergency care?	None Ancillary Care Counseling/Social Support Service Pediatric subspecialties Other: specify	Site specific
7	What is the age of majority in your state?	Text field	Site/state specific
8	What documentation will your research staff use to determine which individual(s) meet the definition of a guardian in accordance with your state and local laws?	Text field	Site specific - defer to local process
9	Will your site allow for a guardian (an individual who is not a parent, but who is authorized under applicable state and local law) to consent on behalf of a child to a research study?	No Yes	Site specific - defer to local process
10	How will your research staff determine who meets the definition of a guardian in accordance with your state and local law?	Text field	Site specific - defer to local process

11	How will your research staff document the legal relationship between the child and guardian?	Text field	Site specific - defer to local process
12	A legally authorized representative (LAR) may be required to provide consent when an adult, non-minor does not have the legal capacity to consent to participation in a research study. Will your site allow the use of an LAR?	No Yes	Yes
13	What documentation will your research staff use to determine if a person meets the criteria for a potential subject's LAR under your state and local laws?	Text field	Site specific
14	How will your research staff document the legal relationship between the subject and the LAR?	Text field	Site specific - defer to local process
15	Indicate any state or local laws having an impact on research at your investigation/research location	· None · Mandatory IRB Site Visits · Age of Majority is 19 years (US states of AL, NE & Canadian provinces of AB, BC, NB, NF, NS) or 21 years for Puerto Rico · California Experimental Subject's Bill of Rights · State Privacy laws related to the use of Protected Health Information (PHI) · Other: specify	Site specific
16	Which, if any, of the following pending or on-going actions or restrictions related to the practice of medicine or research apply at your location(s) [including the PI and the research staff]	· Legal · Regulatory · Professional · Other · None of the above	Site specific
17	If any, explain	Text field	
18	Please provide your FWA number: FWA-	Text field	Site specific
19	How will the subject's data identified be recorded?	· Identifiers will be anonymized, coded, or de-identified as outlines in the protocol or our standard operating procedures/policies · Other	· Identifiers will be anonymized, coded, or de-identified as outlines in the

			protocol or our standard operating procedures/policies
20	If other, specify	Text field	
21	Did the sponsor approve any local IRB requested additions to the informed consent form?	No Yes	
22	Additional language on the informed consent form	Text field	

Step 2: Site Regulatory Inspection History (Form)

pathway: WebDCU SIREN > Central IRB (tile) > Site Regulatory Inspection History
You must complete a new record for each *regulatory inspection* for the Investigator or your research location(s) that have occurred in the last 5 years.
*****If there have been no violations, there is no need to create a record. Form location in WebDCU:

Step 3: Initial Site Submission (Form) for US sites.

Outside of US sites should complete only the Conflict of Interest section. (Questions 52-68)

The cIRB forms in the SIREN database must be completed before this form can be considered complete and ready for CCC review. See Steps 1 & 2.

No.	Item Description	Answer choices	Expected/Allowed Response
2	Site		WebDCU derived
3	Site PI		WebDCU derived
4	Email		WebDCU derived
5	Full Protocol Title		Fixed and derived from Project Overview
6	Protocol Number		Fixed
Investigational/Research Location(s) and Subject Recruitment			
7	Address 1		WebDCU derived
8	Address 2		WebDCU derived
9	City		WebDCU derived
10	State/Province		WebDCU derived
11	Zip/Postal Code		WebDCU derived
12	Country		WebDCU derived
13	Site Type		Derived from Site Overview
14	If Other, specify		Derived from Site Overview
15	How many years has research been conducted at this location?		Derived from Site Overview

16	Selected all research-related activities conducted at this location (check all that apply)	Screening visits Specific Procedures Associated With a Protocol Informed Consent Discussion Ongoing Study Visits Other	Select all
17	Do you have access to the study population (outlined in the protocol) that would allow for recruitment of the necessary number of research subjects?	Yes No	Yes
18	If no, please explain how you plan to recruit the necessary number of participants	Not applicable	Not applicable
19	Is a licensed M.D. or D.O. (who is a member of the research staff) available while subjects are being seen? P-ICECAP requires 24/7 in house critical care medicine settings	Yes No	Yes
20	If no, explain	Text field	Site specific
21	Select all emergency equipment/staff available at this location Dependent on the type of research conducted, emergency and non-emergency medical and/or psychological resources may be		Derived from Site Overview

	necessary to protect research subjects. Check all that apply.		
22	Select all additional resources available that are unrelated to emergency care Check all that apply.		Derived from Site Overview
23	Which of the following subject populations do you plan to enroll for the study? Check all that apply	Pediatric 2 months to <18 years of age Potentially decisionally Impaired/Cognitively Non-English Speaking	
24	Please confirm you are not targeting any population for enrollment other than those required by the study design (inclusion criteria)	I do not confirm I confirm	I confirm
25	If you selected [I do not confirm] above, please provide specifics here	Text field	
26	How many subjects are expected to be enrolled at your site?	12	Fixed
27	Will your site be billed directly by the IRB?	No	Fixed & derived from Project Overview

29	I confirm that I will follow the statements below regarding protection for minors: a. Any assent document provided by the IRB will be used as directed by the IRB. b. Outside parties (parent/guardian) will not unduly coerce the subject to participate. c. The research study will be explained to the minor in language that they can understand. d. The minor will be given an opportunity to ask questions about the research study without the presence of parent(s)/guardian, if requested and appropriate.	No Yes	Check 'Minors' and 'Non English Speakers'
29	What is the age of majority in your state?		Derived from Site Overview
30	How will your research staff determine who meets the definition of a child in accordance with your state and local laws?		Derived from Site Overview
31	Will your site allow for a guardian (an individual who is not a parent, but who is authorized under applicable state and local law) to consent on behalf of a child to a research study?		Derived from Site Overview

32	How will your research staff determine who meets the definition of a guardian in accordance with your state and local law?		Derived from Site Overview
33	How will your research staff document the legal relationship between the child and the guardian?		Derived from Site Overview
Protections for Potentially Decisionally Impaired/Cognitively Impaired/Mentally Ill Adults			
34	Your confirmation indicates the following: a. The procedure at your investigational/research location(s) for the capacity assessment will include an assessment of at least the topics referenced in section #1 above. b. The assessment will be performed prior to asking the subject to sign the Informed Consent Form document(s). I confirm the below statements:	No Yes	Yes

35	A legally authorized representative (LAR) may be required to provide consent when an adult, non-minor does not have the legal capacity to consent for a child to participate in a research study. Will your site allow the use of an LAR?		Derived from Site Overview
36	How will your research staff determine who meets the criteria for an LAR under your state and local law?		Derived from Site Overview
37	How will your research staff document the legal relationship between the subject and the LAR?		Derived from Site Overview
Regulatory Inspection and IRB Considerations			
38	Have any regulatory inspections occurred at this site in the last 5 years?	No Yes	Sites should ask their local IRB for information about their institution if it is otherwise not known
39	A. Investigator B. Inspection Type C. Start Date D. Stop Date E. Finding	Text field	Site specific
40	Has the research study and/or your site been disapproved or withdrawn from another IRB	No	Fixed & derived from Project Overview

41	If previously or currently approved by another IRB, are you requesting a transfer of IRB Oversight?	No	Fixed & derived from Project Overview
Conflict of Interest			
52	Have any of the above individuals received compensation from a relevant company (e.g., in exchange for consulting, speaking, or serving on an advisory board) that when aggregated for the immediate family for the prior 12 months is $5,000 or greater?	No Yes	Check with PI, Sub-I's, research staff, and their immediate families for answer
53	Please select the amount	Text field	Check with PI, Sub-I's, research staff, and their immediate families for answer
54	Specify exact amount or within $25K range	Text field	Check with PI, Sub-I's, research staff, and their immediate families for answer
55	Describe the specific interest in detail, including the estimated value of interest, percentage of ownership (if applicable), name and role of the conflicted individual, and the arrangement giving rise to the potential conflict (e.g., equity purchased or provided in exchange for services)	Text field	Check with PI, Sub-I's, research staff, and their immediate families for answer

56	Do any of the above individuals have an ownership interest (e.g., stock) in a publicly-held relevant company that when aggregated for the immediate family for the prior 12 months is $5,000 or greater?	No Yes	Check with PI, Sub-I's, research staff, and their immediate families for answer
57	Please select the amount	Text field	Check with PI, Sub-I's, research staff, and their immediate families for answer
58	Specify exact amount or within $25K range	Text field	Check with PI, Sub-I's, research staff, and their immediate families for answer
59	Describe the specific interest in detail, including the estimated value of interest, percentage of ownership (if applicable), name and role of the conflicted individual, and the arrangement giving rise to the potential conflict (e.g., equity purchased or provided in exchange for services)	Text field	Check with PI, Sub-I's, research staff, and their immediate families for answer
60	Do any of the above individuals have any ownership interest (e.g., stock, stock options) in a relevant company that is privately-held?	No Yes	Check with PI, Sub-I's, research staff, and their immediate families for answer
61	Do any of the above individuals have a proprietary interest being investigated in the research study (e.g., patent or licensing agreement)	No Yes	Check with PI, Sub-I's, research staff, and their immediate families for answer

62	Do any of the above individuals have a financial agreement with any company in which they receive, or will receive, compensation that is linked to the outcome of the research study?	No Yes	Check with PI, Sub-I's, research staff, and their immediate families for answer
63	Do any of the above individuals serve as in an executive position or on the board of directors for a relevant company?	No Yes	Check with PI, Sub-I's, research staff, and their immediate families for answer
64	Do any of the above individuals have any other financial or non-financial interests not listed above that could appear to potentially influence the conduct or outcome of this research study at the investigational/research location(s) or interfere with the ability to adequately protect research subjects?	No Yes	Check with PI, Sub-I's, research staff, and their immediate families for answer
65	For each yes answer above, describe the specific interest in detail, including the estimated value of interest, percentage of ownership (if applicable), role of the conflicted individual, and the arrangement giving rise to the potential conflict (e.g., equity purchased or provided in exchange for services)	Text field	Check with PI, Sub-I's, research staff, and their immediate families for answer

66	Has an in-house Institutional Conflict of Interest Committee made any determinations and/or required any specific management plans related to this research for any of the above individuals?	No Yes	Site specific
67	If yes, provide a detailed description of the determinations/management plans	Text field	Site specific
68	If Yes to any questions above, please provide a proposed plan to manage the potential conflict of interest, including any steps required by a COI Committee identified above. Check all that apply	Disclosure of the COI in the informed consent form (language will be provided by Advarra) A non-conflicted member of the study team will obtain informed consent A non-conflicted member of the study team will serve as the PI Only non-conflicted members of study staff will perform data analysis Other specific tasks/roles will be performed by a non-conflicted member of the study team Independent data and safety monitoring will be performed	Site specific

		Additional COI training (such as CITI) will be completed by the conflicted individual Interests giving rise to the COI will be reduced or eliminated prior to the individual engaging in the research Other management step(s)	
57	Please describe the other specific tasks/roles that will be performed by non-conflicted member of the study team	Text field	Site specific
58	Please describe the monitoring details	Text field	Site specific
59	Please specify the COI training to occur and when it is to be completed	Text field	Site specific
60	Please specify how you plan to reduce or eliminate the interests	Text field	Site specific
61	Please provide the details of other management considerations	Text field	Site specific
Informed Consent Document			
62	A. First Name B. Last Name	Text field	Site specific
63	Primary phone number to be listed on the ICF document(s)	Text field	Phone number on the ICF

64	24-Hour phone number to be listed on the ICF document(s)	Text field	Can be the same number as the Primary phone number
65	Provide the breakdown of compensation or reimbursement to subjects, including any gift cards, toys, or movie tickets. If you are not compensating and/or reimbursing subjects, then you can just indicate N/A(SIREN: Project Overview)	N/A	Fixed & derived from Project Overview
66	Timing of Monetary Payments	There will be no payment/reimbursement to subjects	Fixed & derived from Project Overview
67	If “Other”, please provide an explanation of timing of payment below	<leave blank>	Fixed & derived from Project Overview
68	List of visits for which subjects will not be paid	<leave blank>	Fixed & derived from Project Overview
69	Will you need the ICF translated into another language?	Yes	Fixed & derived from Project Overview
70	If yes, what language(s)?	As needed, per site.	Fixed & derived from Project Overview
71	Are you requesting the IRB to grant a partial or full HIPAA Waiver?	<leave blank>	Fixed
Request for HIPAA Waiver			

72	What type of HIPAA Waiver are you requesting?	Request for Partial Waiver of HIPAA Authorization for the purposes of allowing a researcher to obtain protected health information as necessary to recruit potential research subjects.	Fixed
73	Please describe your screening/recruitment method.		Fixed
74	Please describe how the use of PHI for identifying subject eligibility and contacting potential subjects is of minimal risk to the individual's privacy	Brief screening of medical records will be kept strictly confidential under secure conditions. Medical records will only be used as a source document for clinical study participation if the patient becomes a subject.	Fixed
75	When will screening data be either de-identified or destroyed? (generally a statement that ineligible patient's PHI will not be shared with the sponsor, and it will be destroyed or placed in a secure file until it can be destroyed)	To maintain compliance with recruitment procedures, a de-identified screen failure log will be completed for all non-randomized patients who were screened for the HOBIT Trial. The screen failure log will be stored in a secure file on site until it can be destroyed	Fixed
76	Please describe why recruitment cannot be carried out without the Partial Waiver of Authorization to use a potential subject's PHI	Potential subjects could not be screened for eligibility without reviewing medical information to determine patient eligibility. The team will briefly review and screen health information to determine eligibility and inclusion / exclusion criteria as required by the study protocol.	Fixed

Investigator Experience and Qualifications			
77	How many years has the PI been involved in the conduct of research?	None (new to research) Less than 1 year 1 or more years	Site specific - no right answer
78	What additional training, certifications, and/or degrees in the field of human research protections have been completed by the Investigator?	OHRP Human Subject Assurance Training NIH Online Course: Human Participant Protections Education for Research Teams Investigator Meeting(s) Collaborative Institutional Training Initiative (CITI) Program APPI [Certified Physician Investigator (CPI™)] ACRP [CTI, CCRC, CCRA] SOCRA [CCRP] Graduate/Undergraduate researcher studies/degree(s) DIA [CCI] Tri Council Policy Statement Course on Research Ethics (CORE) Clinical Research Association of Canada (CRAC) Academy of Physicians in Clinical Research (APCR) Other specify:	Site specific - no right answer
79	What is the current number of research studies supervised by the Investigator?	text field	Site specific - no right answer

80	What is the approximate number of active research subjects currently supervised by the Investigator?	text field	Site specific - no right answer
81	How many Sub-Investigators with clinical trials experience are assisting the Investigator?	text field	Site specific - no right answer
82	How many research staff members with clinical trials experience are assisting the Investigator?	text field	Site specific - no right answer
83	If there are any other resources available at your site to support the administration of any active clinical trials, please provide them here	text field	Site specific - no right answer
Site and Local Context Information			
84	Indicate any state or local laws having an impact on research at your investigational/research location(s) by checking all that apply		Derived from Site Overview
85	Which, if any, of the following pending or on-going actions or restrictions related to the practice of medicine or research apply at your location(s) [including the PI and the research staff]		Derived from Site Overview
86	If any, explain	Text field	
What recruitment methods may be used at your site?			

87-1	In conversation during routine office visits	No	Fixed & derived from Project Overview
87-2	Rollover or extension or participation from another research study	No	Fixed & derived from Project Overview
87-3	Mass distributed print publication (ex: newspaper, magazine, newsletter)	No	Fixed & derived from Project Overview
87-4	Flyer, poster or bulletin board	No	Fixed & derived from Project Overview
87-5	Radio	No	Fixed & derived from Project Overview
87-6	Television	No	Fixed & derived from Project Overview
87-7	Direct Mailing	No	Fixed & derived from Project Overview
87-8	Internet	No	Fixed & derived from Project Overview
87-9	Database/Chart Review	No	Fixed & derived from Project Overview
87-10	Telephone Screening Script	No	Fixed & derived from Project Overview
87-11	Other	Yes	Fixed & derived from Project Overview

87-12	If Other, specify	Potential subjects are identified through trauma team activations, direct communication with clinical providers; and use of emergency department information technology systems as documented in the HOBIT MOP section 3.1 and Protocol section 5.4	Fixed & derived from Project Overview
88	Will you be paying any professionals for their assistance in the recruitment of potential subjects	No	Fixed & derived from Project Overview
89	If Yes, explain	Text field	
90	Do any of your research location(s) have a local IRB that the PI is required to submit to?	Yes	Fixed
91	If Yes, your research location(s) have a local IRB that the PI is required to submit to	An Oversight waiver (Local IRB trial Acknowledgment) will be provided Our site is a member of SMART IRB	Site specific
92	FWA Number		Derived from Site Overview
93	FWA Reg Doc		Document is pulled in from webDCU
94	How would you describe the attitudes about research held by potential research subjects in your community?	Positive Neutral Negative	Positive – most likely

95	If Negative, explain	Text field	Site specific
96	Has there been any recent media focus on research in your community?	No Yes	Site specific
97	If Yes, explain	Text field	Site specific
Informed Consent Process, Data Privacy and Confidentiality			
98	Do you (the Investigator) and your research staff (if applicable) agree to comply with the conditions regarding the informed consent process as outlined above?	I agree with the process I disagree	I agree with the process
99	If you do not agree, provide an explanation	Text field	
100	Do you conduct competing research studies?	No Yes	Site specific
101	You indicated that you conduct competing research studies. Do you confirm that the potential subject (or their LAR) and the PI will be involved in the decision?	No Yes	Site specific
102	Please specify the location at your site where the informed consent process will be conducted with a potential subject (or their LAR)	In a private room/area In a group setting Other explain:	Site specific - no right answer
103	Please specify the steps taken by the Investigator and authorized research staff to minimize the possibility of	The informed consent discussion is presented to the subject (or their LAR) by someone who is sufficiently	All should be checked

	coercion or undue influence during the informed consent process	knowledgeable about the research to properly interpret and correctly answer questions. The subject (or their LAR) is not pressured to participate in the research and is not penalized or excessively questioned for deciding not to participate in the research. The consent presentation is discussed in non-technical language understandable to the subject (or their LAR) and the subject's (or LAR's) understanding is confirmed through an unrushed two-way conversation. Other	
104	Please specify the steps taken by the Investigator and authorized research staff to ensure that the subject (or their LAR) is provided sufficient opportunity to consider participation in the research.	The subject (or their LAR) is given adequate time and place to read and review the Informed Consent Form and ask questions. The subject (or their LAR) is given the opportunity to take the Informed Consent Form home for review prior to signing the document.	All should be checked

		The subject (or their LAR) is provided a sufficient waiting period between being informed of the research and signing the consent form. Other	
105	How will the subject's data identifiers be recorded?		Derived from Site Overview
106	If Other, specify		Derived from Site Overview
107	Choose all the mechanisms in place to ensure that the research records/data will be kept to protect the privacy and confidentiality of subject information.	Paper-based records will be kept in a secure location only accessible to authorized staff Computer-based files will be available only to authorized staff using access privileges and passwords Other	all should be checked
108	Did the sponsor approve any local IRB requested additions to the informed consent form?	No Yes	Site specific
109	Additional language on the informed consent form	Text field	Site specific
Document Uploads			

110	Investigator Medical License Number	Text field	PI Medical License
111	PI Medical License	pdf	Pdf pulled in from WebDCU
112	CV of Investigator	pdf	Pdf pulled in from WebDCU
113	Conflict of Interest	Pdf	Pdf pulled in from WebDCU
114	Local IRB Trial Acknowledgement	pdf	Pdf pulled in from WebDCU