HOBIT Regulatory Documents, Readiness, and Site Start Up

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HOBIT SITE MANAGER

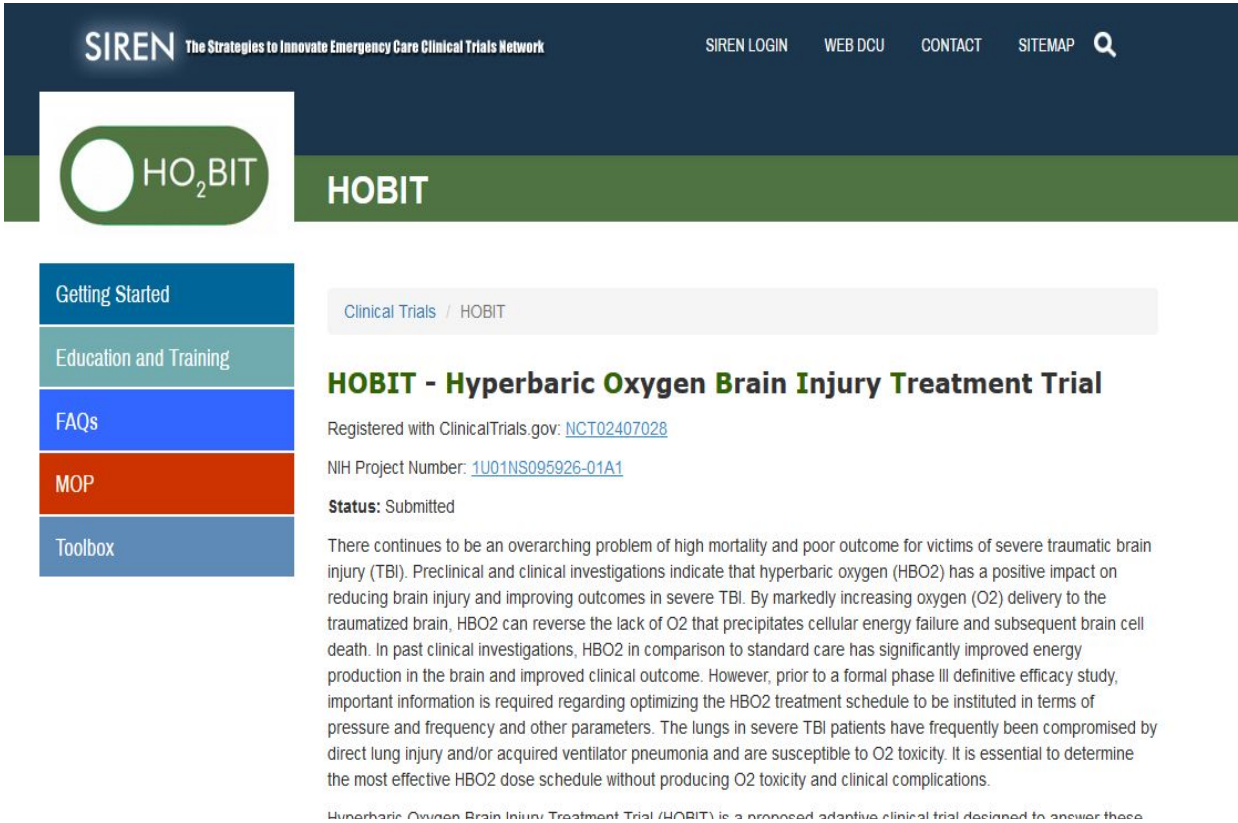
HOBITTRIAL.org

Locate study materials

- Protocol
- Regulatory Parameters Document
- MOP
- Readiness Checklist

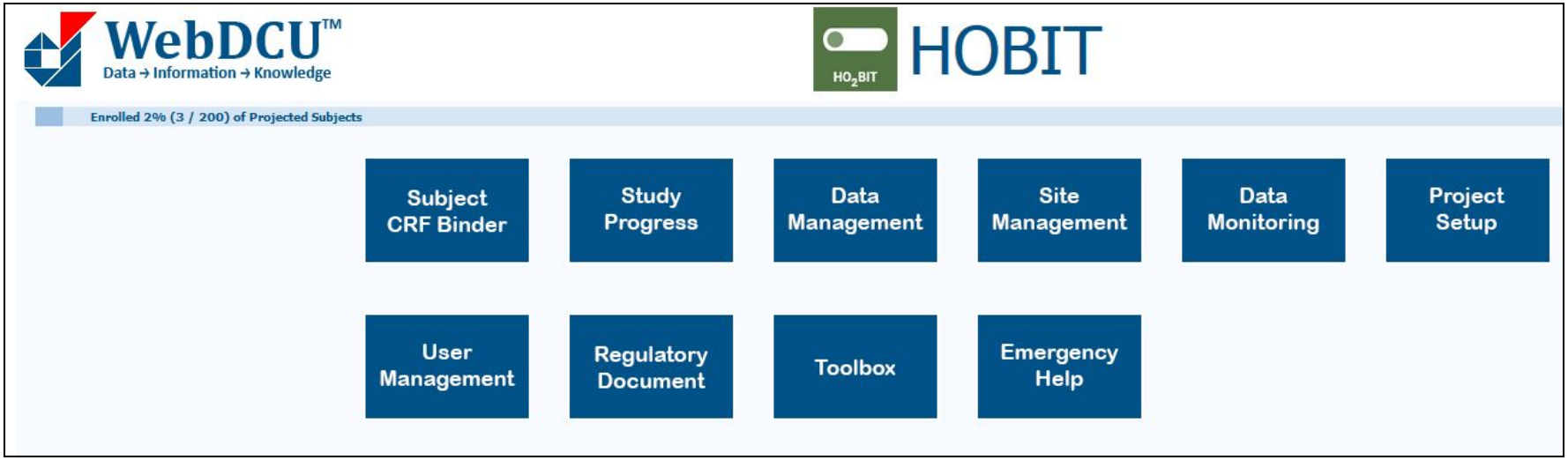
Access training materials

- HOBIT Data & Regulatory Training



HOBIT Regulatory Database: WebDCU

- HOBIT regulatory database will serve as the central repository for regulatory documents



Reminder: Please upload all documents as pdfs in WebDCU

Regulatory Requirements for Site Startup: eDOA Log

- Electronic Delegation of Authority (eDOA) Log
- Roles and Responsibilities = Regulatory Parameters Document

Team Member Request																			
Team Member	Start Date	PI	CoI	PSC	SSC	RDC	Adm	HPI	HPM	A	B	C	D	E	F	G	H	I	J	K	L
Records Entered																					

Study Roles	PI - Principal Investigator CoI - Co-Investigator PSC - Primary Study Coordinator	SSC - Secondary Study Coordinator RDC - Regulatory Document Coordinator Adm - Administrator	HPI - Hub PI HPM - Hub Project Manager
DOA Responsibilities	A - Overall responsibility for the trial B - Obtain Informed consent C - Assess/Report AEs D - Complete CRFs/respond to queries	E - Maintain regulatory compliance in WebDCU F - Determine eligibility (Inclusion/Exclusion) G - Clinical assessment/daily monitoring H - Administration of study interventions	I - Internal SIREN hub/spoke verification J - Ongoing team training/protocol compliance K - Administer GOSE L - CT Scan accountability

Regulatory Parameters Document

Regulatory Document Approval Parameters for WebDCU™
HOBIT

Site 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™
FWA	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™. Please see FWA process document in the HOBIT Toolbox. Provide source in a pdf attachment.
CLIA	site	Use source	Use source	No	CLIA certification is the only lab certification required. Provide source in a pdf attachment.
FDA Form 1572	site	Use date document was signed	No - leave blank	No	Provide source as a pdf attachment. NOTE: All study team members performing the following responsibilities MUST be on the 1572: overall responsibility for the trial, informed consent, AE/SAE reporting. All investigators should be listed as well. Provide source in a pdf attachment.
Attestation of Study Team Education & Training	site	Use date signature provided	No - leave blank	No	Each Spoke 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 HOBIT subjects at their spoke. Please print the signature page of the current protocol and upload the PI signed and dated pdf attachment in WebDCU™.

Regulatory Parameters Document: People Documents

All Team Members

- CV
- HSP
- GCP
- Protocol Training

Applicable Team Members

- Medical License
- HOBIT Data Training
- Regulatory Document Training
- GOSE Certification

Reminder: Please upload all documents as pdfs in WebDCU

Regulatory Parameters Document: Site Documents

- FWA
- CLIA Certification
- FDA Form 1572
  - IRB Approval
  - IRB Approved Informed Consent
- Attestation of Study Team Education and Training
- Local IRB Trial Acknowledgment
- HSP Requirements
- Clinical Research Budget Attestation (Canadian sites only)

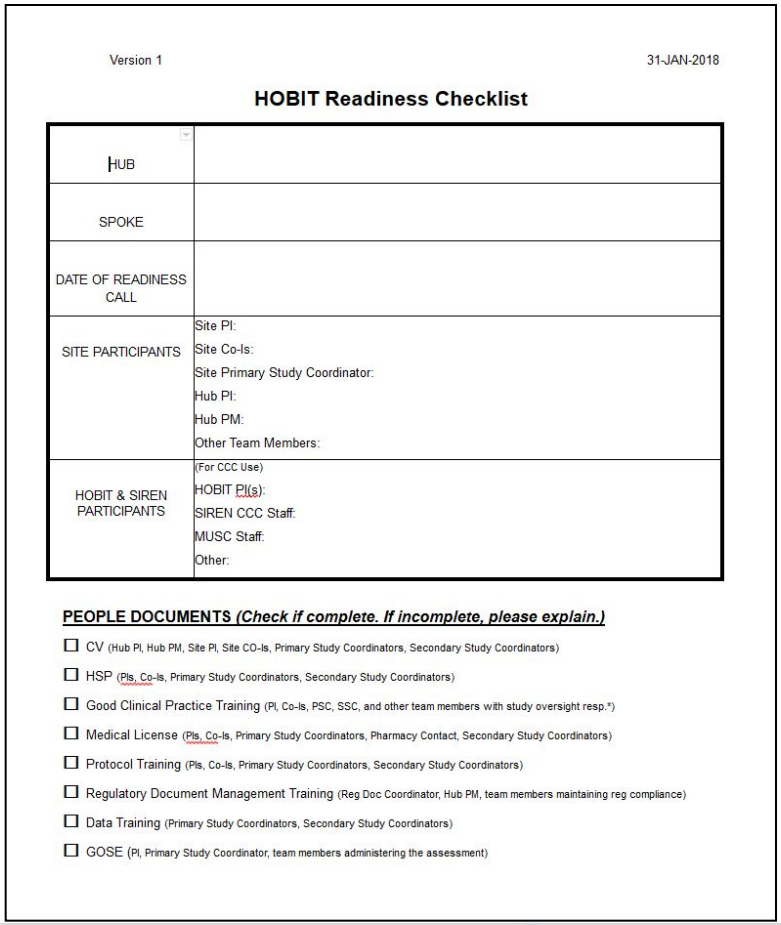
Reminder: Please upload all documents as pdfs in WebDCU

Regulatory Requirements for Site Startup: Readiness Call

- A Readiness Call is the Study Initiation Meeting
- Conducted via phone conference
- Evaluate and confirm site readiness for study activation
- Q&A with trial leadership and CCC
- Site Personnel: Hub PI and PM, Trial PI, Primary Study Coordinator

Regulatory Requirements for Site Startup: Readiness Checklist

- Sites will complete to confirm regulatory and logistical readiness
- Completed by study team and used as agenda for the readiness call
- Readiness Checklist is on hobittrial.org



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HOBIT Readiness Checklist

HUB	
SPOKE	
DATE OF READINESS CALL	
SITE PARTICIPANTS	Site PI: Site Co-Is: Site Primary Study Coordinator: Hub PI: Hub PM: Other Team Members:
HOBIT & SIREN PARTICIPANTS	(For CCC Use) HOBIT PI(s): SIREN CCC Staff: MUSC Staff: Other:

PEOPLE DOCUMENTS ***(Check if complete. If incomplete, please explain.)***

- ☐ CV (Hub PI, Hub PM, Site PI, Site CO-Is, Primary Study Coordinators, Secondary Study Coordinators)
- ☐ HSP (PIs, Co-Is, Primary Study Coordinators, Secondary Study Coordinators)
- ☐ Good Clinical Practice Training (PI, Co-Is, PSC, SSC, and other team members with study oversight resp.*)
- ☐ Medical License (PIs, Co-Is, Primary Study Coordinators, Pharmacy Contact, Secondary Study Coordinators)
- ☐ Protocol Training (PIs, Co-Is, Primary Study Coordinators, Secondary Study Coordinators)
- ☐ Regulatory Document Management Training (Reg Doc Coordinator, Hub PM, team members maintaining reg compliance)
- ☐ Data Training (Primary Study Coordinators, Secondary Study Coordinators)
- ☐ GOSE (PI, Primary Study Coordinator, team members administering the assessment)

Regulatory Requirements for Site Startup: Readiness Call

Post Call - Site Activation

- If action items, site personnel will resolve prior to activation
- If no action items, site will be activated and released to enroll
- HOBIT and study team notified via email

Ongoing Site Management

- It is the responsibility of each Hub/Site to maintain regulatory compliance
  - Site Documents and People Documents
- Documents approaching expiration should be reconciled prior to the expiration date
  - Automated emails will be sent for expiring, expired, and missing documents as well as an alerts tab
- Study team personnel who are out of regulatory compliance should not participate in any trial related activities

Study Team Changes

- Add to HOBIT Database
- Amend FDA 1572 forms
- Update eDOA
- Upload all team personnel documents, trainings and certifications (eg. CV, medical license)

Who to Contact?

Site Management & Regulatory
Natalie Fisher
brownnat@umich.edu

WebDCU
Jodie Riley & Teldon Alford
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alfordt@musc.edu

Hobittrial.org
Joy Black
joypink@umich.edu

Emergency Hotline
833-HOBIT-PI (833-462-4874)

All contact information is available on hobittrial.org

Questions?