HOBIT Initial Site Submission Parameters Document in WebDCU

No.	WebDCU Location	Item Description	Answer choices	Expected/Allowed Response
1		Hub		WebDCU derived
2	drop down menu	Site		WebDCU derived
3	eDOA	Site PI		WebDCU derived
4	Site table	Email		WebDCU derived
5	SIREN: Project Overview	Full Protocol Title		fixed
6	SIREN: Project Overview	Protocol Number		fixed
Investigational/Research Location(s) and Subject Recruitment				
7	Site table	Address 1		WebDCU derived
8	Site table	Address 2		WebDCU derived
9	Site table	City		WebDCU derived
10	Site table	State/Province		WebDCU derived
11	Site table	Zip/Postal Code		WebDCU derived
12	Site table	Country		WebDCU derived
13	SIREN: Site Overview	Site Type	Research dedicated facility Private/group practice Hospital or hospital affiliated University or university Affiliated Psychiatric institution Residential facility Other	University or university affiliated Hospital or hospital affiliated

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14	SIREN: Site Overview	If Other, specify	Text field	
15	SIREN: Site Overview	How many years has research been conducted at this location?	less than 1 1-3 3 or more	Site specific – no right answer
16	HOBIT: cIRB Initial Site Sub	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	HOBIT: cIRB Initial Site Sub	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	HOBIT: cIRB Initial Site Sub	If no, please explain how you plan to recruit the necessary number of participants	Not applicable	Not applicable
19	HOBIT: cIRB Initial Site Sub	Is a licensed M.D. or D.O. (who is a member of the research staff) available while subjects are being seen?	Yes No	Yes
20	HOBIT: cIRB Initial Site Sub	If no, explain	Text field	

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21	SIREN: Site Overview	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 necessary to protect research subjects. Check all that apply.	Crash Cart Emergency drugs [i.e. Benadryl/Epinephrine] Access to 911 In-house 'Code' Defibrillator Oxygen CPR Certified Staff Other specify:	Select all
22	SIREN: Site Overview	Select all additional resources available that are unrelated to emergency care Check all that apply.	None Ancillary Care Counseling/Social Support Service Other specify:	Site specific – no right answer
23	HOBIT: cIRB Initial Site Sub	Which of the following subject populations do you plan to enroll for the study? Check all that apply	Adults Minors (subjects under the age of majority) Potentially decisionally Impaired/Cognitively	Site specific Adults minors (if applicable) potentially decisionally impaired/Cognitively
24	HOBIT: cIRB Initial Site Sub	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		
26	HOBIT: cIRB Initial Site Sub	How many subjects are expected to be enrolled at your site?	13	Fixed
27	SIREN: Project Overview	Will your site be billed directly by the IRB?	No	Fixed

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28	HOBIT: cIRB Initial Site Sub	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	If enrolling minors - Yes
29	SIREN: Site Overview	What is the age of majority in your state?	text field	no right answer, defer to local law
30	SIREN: Site Overview	How will your research staff determine who meets the definition of a child in accordance with your state and local laws?	text field	no right answer. defer to local law
31	SIREN: Site Overview	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	Yes
32	SIREN: Site Overview	How will your research staff determine who meets the definition of a guardian in accordance with your state and local law?	text field	no right answer, defer to local process

Protections for Potentially Decisionally Impaired/Cognitively Impaired/Mentally Ill Adults				
No.	**WebDCU Location**	**Item Description**	**Answer choices**	**Expected/Allowed Response**
33	SIREN: Site Overview	How will your research staff document the legal relationship between the child and the guardian?	text field	no right answer, defer to local process
34	HOBIT: cIRB Initial Site Sub	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	SIREN: Site Overview	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
36	SIREN: Site Overview	How will your research staff determine who meets the criteria for an LAR under your state and local law?	text field	no right answer, defer to local process

No.	WebDCU Location	Item Description	Answer choices	Expected/Allowed Response
37	SIREN: Site Overview	How will your research staff document the legal relationship between the subject and the LAR?	text field	no right answer, defer to local process
Regulatory Inspection and IRB Considerations				
38	HOBIT: cIRB Initial Site Sub	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
40	SIREN: Project Overview	Has the research study and/or your site been disapproved or withdrawn from another IRB	No	fixed
41	SIREN: Project Overview	If previously or currently approved by another IRB, are you requesting a transfer of IRB Oversight?	No	fixed
Conflict of Interest				
42	HOBIT: cIRB Initial Site Sub	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) and/or 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 greater than $5,000	No Yes	Check with PI, Co-I's, research staff, and their immediate families for answer
43	HOBIT: cIRB Initial Site Sub	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, Co-I's, research staff, and their immediate families for answer

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44	HOBIT: cIRB Initial Site Sub	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, Co-I's, research staff, and their immediate families for answer
45	HOBIT: cIRB Initial Site Sub	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, Co-I's, research staff, and their immediate families for answer
46	HOBIT: cIRB Initial Site Sub	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, Co-I's, research staff, and their immediate families for answer
47	HOBIT: cIRB Initial Site Sub	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, Co-I's, research staff, and their immediate families for answer
48	HOBIT: cIRB Initial Site Sub	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, Co-I's, research staff, and their immediate families for answer

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49	HOBIT: cIRB Initial Site Sub	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
50	HOBIT: cIRB Initial Site Sub	If yes, provide a detailed description of the determinations/management plans		
51	HOBIT: cIRB Initial Site Sub	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.	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 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)	Site specific
52	HOBIT: cIRB Initial Site Sub	Please describe the other specific tasks/roles that will be performed by non-conflicted member of the study team	Text field	Site specific
53	HOBIT: cIRB Initial Site Sub	Please describe the monitoring details	Text field	Site specific

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54	HOBIT: cIRB Initial Site Sub	Please specify the COI training to occur and when it is to be completed	Text field	Site specific
55	HOBIT: cIRB Initial Site Sub	Please specify how you plan to reduce or eliminate the interests	Text field	Site specific
56	HOBIT: cIRB Initial Site Sub	Please provide the details of other management considerations	Text field	Site specific
Informed Consent Document				
58	HOBIT: cIRB Initial Site Sub	Primary phone number to be listed on the ICF document(s)	text field	Phone number on the ICF
59	HOBIT: cIRB Initial Site Sub	24-Hour phone number to be listed on the ICF document(s)	text field	can be the same number as the Primary phone number
60	SIREN: Project Overview	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
61	SIREN: Project Overview	Timing of Monetary Payments	There will be no payment/reimbursement to subjects	fixed
63	SIREN: Project Overview	List of visits for which subjects will not be paid	<leave blank>	fixed
64	SIREN: Project Overview	Will you need the ICF translated into another language?	No	fixed

Investigator Experience and Qualifications				
No.	**WebDCU Location**	**Item Description**	**Answer choices**	**Expected/Allowed Response**
66	HOBIT: cIRB Initial Site Sub	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
67	HOBIT: cIRB Initial Site Sub	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
68	HOBIT: cIRB Initial Site Sub	What is the current number of research studies supervised by the Investigator?	text field	Site specific - no right answer
69	HOBIT: cIRB Initial Site Sub	What is the approximate number of active research subjects currently supervised by the Investigator?	text field	Site specific - no right answer
70	HOBIT: cIRB Initial Site Sub	How many Sub-Investigators with clinical trials experience are assisting the Investigator?	text field	Site specific - no right answer
71	HOBIT: cIRB Initial Site Sub	How many research staff members with clinical trials experience are assisting the Investigator?	text field	Site specific - no right answer

No.	WebDCU Location	Item Description	Answer choices	Expected/Allowed Response
72	HOBIT: cIRB Initial Site Sub	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				
73	SIREN: Site Overview	Indicate any state or local laws having an impact on research at your investigational/research location(s) by checking all that apply	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 explain:	Site specific - no right answer
74	SIREN: Site Overview	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	None of the above - most likely.
75	SIREN: Project Overview	If any, explain		
What recruitment methods may be used at your site?				
76-1	SIREN: Project Overview	In conversation during routine office visits	No	Fixed
76-2	SIREN: Project Overview	Rollover or extension or participation from another research study	No	Fixed

No.	WebDCU Location	Item Description	Answer choices	Expected/Allowed Response
76-3	SIREN: Project Overview	Mass distributed print publication (ex: newspaper, magazine, newsletter)	No	Fixed
76-4	SIREN: Project Overview	Flyer, poster or bulletin board	No	Fixed
76-5	SIREN: Project Overview	Radio	No	Fixed
76-6	SIREN: Project Overview	Television	No	Fixed
76-7	SIREN: Project Overview	Direct Mailing	No	Fixed
76-8	SIREN: Project Overview	Internet	No	Fixed
76-9	SIREN: Project Overview	Database/Chart Review	No	Fixed
76-10	SIREN: Project Overview	Telephone Screening Script	No	Fixed
76-11	SIREN: Project Overview	Other	No	Fixed
76-12	SIREN: Project Overview	If Other, specify	<blank>	Fixed

No.	WebDCU Location	Item Description	Answer choices	Expected/Allowed Response
77	SIREN: Project Overview	Will you be paying any professionals for their assistance in the recruitment of potential subjects	No	fixed
78		If Yes, explain		
79	HOBIT-Fixed	Do any of your research location(s) have a local IRB that the PI is required to submit to?	Yes	fixed
80	HOBIT: cIRB Initial Site Sub	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
81	SIREN: Site Overview	FWA Number	text field	Site FWA number
82	SIREN: Site Overview	FWA Reg Doc		Document is pulled in from webDCU
83	HOBIT: cIRB Initial Site Sub	How would you describe the attitudes about research held by potential research subjects in your community?	Positive Neutral Negative	Positive – most likely
84		If Negative, explain	Text field	Site specific
85	HOBIT: cIRB Initial Site Sub	Has there been any recent media focus on research in your community?	No Yes	Site specific
86		If Yes, explain	Text field	Site specific
Informed Consent Process, Data Privacy and Confidentiality				
87	HOBIT: cIRB Initial Site Sub	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

No.	WebDCU Location	Item Description	Answer choices	Expected/Allowed Response
88		If you do not agree, provide an explanation	Text field	
89	HOBIT: cIRB Initial Site Sub	Do you conduct competing research studies?	No Yes	Site specific
90	HOBIT: cIRB Initial Site Sub	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?	text field	Site specific
91	HOBIT: cIRB Initial Site Sub	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
92	HOBIT: cIRB Initial Site Sub	Please specify the steps taken by the Investigator and authorized research staff to minimize the possibility of coercion or undue influence during the informed consent process	The informed consent discussion is presented to the subject (or their LAR) by someone who is sufficiently 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	all should be checked

No.	WebDCU Location	Item Description	Answer choices	Expected/Allowed Response
93	HOBIT: cIRB Initial Site Sub	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. The subject (or their LAR) is provided a sufficient waiting period between being informed of the research and signing the consent form. Other	all should be checked
94	SIREN: Site Overview	How will the subject's data identifiers be recorded?	Identifiers will be anonymized, coded, or de-identified as outlined in the protocol or our standard operating procedures/policies Other	Identifiers will be anonymized, coded, or de-identified as outlined in the protocol or our standard operating procedures/policies
95	SIREN: Site Overview	If Other, specify	Text field	Site specific – no right answer
96	HOBIT: cIRB Initial Site Sub	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
Document Uploads				
97	HOBIT: cIRB Initial Site Sub	Investigator Medical License Number	text field	PI Medical License

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98	HOBIT: cIRB Initial Site Sub	PI Medical License	pdf	Pdf pulled in from webDCU
99	(HOBIT: People Reg Doc)	CV of Investigator	pdf	Pdf pulled in from webDCU
100	(HOBIT: People Reg Doc)	Conflict of Interest	Pdf	Pdf pulled in from webDCU
101	(HOBIT: People Reg Doc)	Local IRB Trial Acknowledgement	pdf	Pdf pulled in from webDCU