

## Data Dictionary Codebook

05-15-2025 06:22

[^ Collapse all instruments](#)

#	Variable / Field Name	Field Label <i>Field Note</i>	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)
Instrument: <b>IRB</b> (irb)			<a href="#">^ Collapse</a>
1	record_id	Sidra IRB number	text
2	irbnetnumber	IRBNet allocated number	text
3	old_number	Old allocated number, i.e. some documents might have that number associated to it.	text
4	lpi_irb_org	LPI IRB [pi_name]	text
5	lpi_irb	LPI IRB	sql (autocomplete) <pre>select q1.record,CONCAT(q1.record,' (','q1.first_name',' ',q1.last_name,')')from ( select q.record,max(q.first_name) first_name ,max(q.last_name) last_name from ( select RECORD, case when field_name='first_name' then value end as first_name, case when field_name='last_name' then value end as last_name from redcap.redcap_data where project_id=24 and field_name in ('first_name','last_name') ) q group by q.record) q1;</pre>
6	add_notification_email_irb	Select Additional Email to receive Notifications	sql (autocomplete) <pre>select q1.record,CONCAT(q1.record,' (','q1.first_name',' ',q1.last_name,')')from ( select q.record,max(q.first_name) first_name ,max(q.last_name) last_name from ( select RECORD, case when field_name='first_name' then value end as first_name, case when field_name='last_name' then value end as last_name from redcap.redcap_data where project_id=24 and field_name in ('first_name','last_name') ) q group by q.record) q1;</pre>
7	lpi_notification_email	LPI Notification Email	text (email) Field Annotation: @READONLY @HIDDEN @CALCTEXT(if([lpi_irb]<>"" , [lpi_irb], 'not-assigned@sidra.org'))
8	title_of_irb	Title of IRB [project_title]	notes, Required
9	short_title1	Short, catchy title, for better recognition:	text Field Annotation: @CHARLIMIT=40
10	internal_rdm_check	This is internal to RDM!!!!!! Please note that, the database view vw_irb_protocol_type has dependence on below field so if you make any changes make sure edit this view as well accordingly.	descriptive Field Annotation: @HIDDEN

11	protocol_type	Protocol TypeIRBNet first: [first_sub_type_active]IRBNet actual: [first_actual_review_active]	dropdown (autocomplete), Required		
			1	Exempt	
			2	Expedited	
			3	Full Board	
			4	Non-Human Subjects Research	
			6	Quality Improvement Category (QI)	
			5	In Process	
			10	Closed - (Exempt)	
			22	Closed - (Exempt - Administratively)	
			11	Closed - (Expedited)	
			21	Closed - (Expedited - Administratively)	
			12	Closed - (Full Board)	
			19	Closed (Non-Human Subjects Research)	
			20	Closed Administratively by IRB Office (before any approval)	
			13	Suspended (Expedited)	
			14	Suspended (Full Board)	
			15	Temp Suspended (Exempt)	
			16	Temp Suspended (Expedited)	
			17	Temp Suspended (Full Board)	
			18	Cancelled	
			23	Not Approved	
			24	Terminated	
12	interventional_yn	Is your study an interventional clinical study?IRBNet answer: [clinical_trial]	yesno		
			1	Yes	
			0	No	
13	initial_approval_date	Initial approval dateIRBNet: [initial_approval_active]	text (date_dmy)		
14	expiry_date	Comment on Expiry date	text		
15	expiry_date_2	Expiry date IRBNet info: [expiration_date_active]	text (date_dmy), Required		
16	status_irbnet  Show the field ONLY if: [expiry_date_2] > '[expiry_date_2]'	Status IRBNet(to track the expired protocols)	radio		
			1	No activity shown from PI	
			2	Work in Progress (not submitted)	
			3	Pending Review	
			4	Pending PI action	
			5	Approved	
17	activestatusirb	Is that IRB active? IRBNet entry: [current_pro_status_active]	dropdown, Required		
			1	Yes	
			2	No	
18	reason_subjectenrollment	Section Header: Reason for Subject enrollment	checkbox		
			1	reason_subjectenrollment__1	Sample Collection
			2	reason_subjectenrollment__2	Data Collection
			3	reason_subjectenrollment__3	Questionnaire
			4	reason_subjectenrollment__4	Patient Assessment
			5	reason_subjectenrollment__5	Chart Review
			10	reason_subjectenrollment__10	Other
19	otherreason1  Show the field ONLY if: [reason_subjectenrollment(10)] = '1'	Please define "Others":	text		

20	number_of_subjects_triage	Please say more about the subject enrollment:	checkbox, Required	
			1	number_of_subjects_triage__1 The study is aiming to recruit a limited number of subject
			2	number_of_subjects_triage__2 The study is aiming to collect all subjects with a specific criteria (no limit in IRB)
			3	number_of_subjects_triage__3 A subject limitation is not relevant for this study.
			5	number_of_subjects_triage__5 Mentioned maximal number of subjects / dataset etc.
			4	number_of_subjects_triage__4 Other
21	criteri_nolimit  Show the field ONLY if: [number_of_subjects_triage (2)] = '1'	Briefly describe criteria:	text	
22	explain_more_recruitment  Show the field ONLY if: [number_of_subjects_triage (3)] = '1' or [number_of_subjects_triage(4)] = '1'	Please define in more detail your selection of "Other" or "Subject limitation is not relevant for this study":	text	
23	collecting_institute	Collecting Institution	checkbox	
			1	collecting_institute__1 Sidra
			2	collecting_institute__2 HMC
			3	collecting_institute__3 PHCC
			4	collecting_institute__4 QBB/QGP
			7	collecting_institute__7 Abroad
			6	collecting_institute__6 Others
24	other_collect1  Show the field ONLY if: [collecting_institute(6)] = '1'	Please define "Other" or "Abroad" institution:	text	
25	subject_number	Total number of subjects approved, as per IRB application:IRBNet: [overall_number_of_participants] Consent Form: [number_of_subjects_q] [text_number_of_subjects] <i>a number only, no text</i>	text (number)	
26	is_this_protocol_using_sam	Is this protocol using samples from patients required under another Sidra Medicine protocol ?	yesno	
			1	Yes
			0	No
27	what_is_the_source_protoco  Show the field ONLY if: [is_this_protocol_using_sam]= 1	What is the source protocol :	sql (autocomplete)	
			SELECT q2.record, CONCAT(q2.record, '-', CASE WHEN q2.expiry_date - q2.initial_approval_date = 0 THEN 'NA' ELSE q2.expiry_date END, '-', vipt.value) AS irb FROM ( SELECT q1.record, MAX(q1.expiry_date) AS expiry_date, MAX(q1.initial_approval_date) AS initial_approval_date, MAX(q1.protocol_type) AS protocol_type FROM ( SELECT record, CASE WHEN field_name = 'expiry_date_2' THEN value END AS expiry_date, CASE WHEN field_name = 'initial_approval_date' THEN value END AS initial_approval_date, CASE WHEN field_name = 'protocol_type' THEN value END AS `protocol_type` FROM redcap.redcap_data WHERE project_id = 21 AND field_name IN ('expiry_date_2' , 'protocol_type', 'initial_approval_date')) q1 GROUP BY q1.record) q2 left join redcap.vw_irb_protocol_type vipt on (vipt.code COLLATE utf8mb4_general_ci =q2.q2.protocol_type);	

28	val_subject_number	Validation of Subject enrollment	calc Calculation: if([subject_number]="",0,[subject_number]) Field Annotation: @HIDDEN																					
29	sidra_subjects1  Show the field ONLY if: [number_of_subjects_triage(1)] = '1' and [collecting_institute(1)] = '1' and ([collecting_institute(2)] = '1' or [collecting_institute(3)] = '1' or [collecting_institute(4)] = '1' or [collecting_institute(7)] = '1' or [collecting_institute(6)] = '1')	Number of Subjects planned to be enrolled at Sidra ONLY: (IRBNet: [number_participants_sidra_only]) <i>a number only, no text</i>	text (number)																					
30	val_sidra_subjects1	Validation on subjects enrolled at Sidra only.	calc Calculation: if([sidra_subjects1]="",0,[sidra_subjects1]) Field Annotation: @HIDDEN																					
31	outside_sidra_subject  Show the field ONLY if: [number_of_subjects_triage(1)] = '1' and [collecting_institute(1)] = '1' and ([collecting_institute(2)] = '1' or [collecting_institute(3)] = '1' or [collecting_institute(4)] = '1' or [collecting_institute(7)] = '1' or [collecting_institute(6)] = '1')	Number of Subjects planned to be enrolled OUTSIDE Sidra: <i>a number only, no text</i>	text (number)																					
32	parentssibbling_collect  Show the field ONLY if: [number_of_subjects_triage(1)] = '1' or [number_of_subjects_triage(2)] = '1'	Is the enrollment of parents and/or siblings planned as well? (i.e. in addition to the number of planned subjects)	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No																	
1	Yes																							
0	No																							
33	val_outside_sidra_subject	Validation Subject number enrolled outside Sidra	calc Calculation: if([outside_sidra_subject]="",0,[outside_sidra_subject]) Field Annotation: @HIDDEN																					
34	totalnumber1	Calculation number of total subjects approved as per IRB application (all sides, if Sidra and others)	calc Calculation: [val_sidra_subjects1]+[val_outside_sidra_subject] Field Annotation: @HIDDEN																					
35	def_retro_pro	Section Header:  Here you can look at definitions to Retrospective and Prospective Studies.	descriptive																					
36	retro_or_pro	Is your study a retrospective or prospective? IRBNet Info: [procedures_admin_drug], [procedures_medical_device], [procedures_coll_blood_sampel][procedures_pros_coll1], [procedures_prosp_coll2], [procedures_material][procedures_records], [procedures_video], [procedures_behaviour][procedures_education], [procedures_taste], [procedures_other1][procedures_other2]	checkbox <table><tr><td>1</td><td>retro_or_pro__1</td><td>Retrospective Study</td></tr><tr><td>2</td><td>retro_or_pro__2</td><td>Prospective Study</td></tr><tr><td>3</td><td>retro_or_pro__3</td><td>Case-Control studies (usually but not exclusively retrospective)</td></tr><tr><td>4</td><td>retro_or_pro__4</td><td>Cohort studies (usually but not exclusively prospective)</td></tr><tr><td>5</td><td>retro_or_pro__5</td><td>Use of samples, unidentified, i.e. called: non-human subject research (e.g. for cell lines, or test of methods)</td></tr><tr><td>6</td><td>retro_or_pro__6</td><td>Use of de-identified samples, collected by a different protocol</td></tr><tr><td>10</td><td>retro_or_pro__10</td><td>Other</td></tr></table>	1	retro_or_pro__1	Retrospective Study	2	retro_or_pro__2	Prospective Study	3	retro_or_pro__3	Case-Control studies (usually but not exclusively retrospective)	4	retro_or_pro__4	Cohort studies (usually but not exclusively prospective)	5	retro_or_pro__5	Use of samples, unidentified, i.e. called: non-human subject research (e.g. for cell lines, or test of methods)	6	retro_or_pro__6	Use of de-identified samples, collected by a different protocol	10	retro_or_pro__10	Other
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6	retro_or_pro__6	Use of de-identified samples, collected by a different protocol																						
10	retro_or_pro__10	Other																						
37	other_retropro  Show the field ONLY if: [retro_or_pro(10)] = '1'	Please define other:	text																					
38	comment_to_protocol_status	Comment to Protocol Status	text																					
39	comments	Comments	text																					
40	to_do_irb	To-do List	text																					

41	projects	Projects	<div>sql (autocomplete)</div> <div>select distinct rd.record as record, case when p.project is null then 'NA' else p.project end as project from redcap.redcap_data rd left join (select value,group_concat(record SEPARATOR ',') as project from redcap.redcap_data where project_id=20 and field_name='irb_protocol_no' group by value )p on(rd.record=p.value) where rd.project_id=21 and rd.field_name='record_id';</div>	
			Field Annotation: @HIDDEN	
42	pmohandlingirb	<div>Section Header: <i>Relation to Project Overview</i></div> <div>PMO handling of this IRB</div>	<div>radio</div> <div><div>1</div><div>This IRB is part of one or more projects and will be linked</div></div> <div><div>2</div><div>This IRB does not need project registration</div></div>	
			Field Annotation: @HIDDEN	
43	whynoproject <div>Show the field ONLY if: [pmohandlingirb] = '2'</div>	Explain why it does not need project registration	<div>dropdown</div> <div><div>1</div><div>Social Science / Administration e.g. for Advanced Degree of Staff Member</div></div> <div><div>2</div><div>Project to improve quality of standard procedures</div></div> <div><div>10</div><div>Other</div></div>	
44	furtherwhynoproject <div>Show the field ONLY if: [whynoproject] = '10'</div>	Please provide further description, why no project registration is necessary:	text	
45	irbnetmentionsdr	IRBNet project connection: [sdr_number]	descriptive	
46	project_list	List of Projects: [projects]	descriptive	
47	linktooverview1	Link to the Overview of Research Activity at Sidra	descriptive	
48	irb_approval_letter	<div>Section Header: <i>Documents Please use "IRB Regulatory Binder Documents"</i></div> <div><i>Column for more Document upload. (here limited to: Approval letter, Proposal, IRBNet Application)</i></div> <div>IRB Decision Letter</div> <div><i>IRB Decision Letter</i></div>	file, Required	
49	irb_reliance_form	IRB Reliance Form	file	
50	initial_approval_letter	Initial approval letter <i>First ever approval letter</i>	file Field Annotation: @HIDDEN	
51	proposal_upload	Research Proposal <i>Proposal</i>	file	
52	protocol_uplod	Protocol <i>Protocol</i>	file Field Annotation: @HIDDEN @READONLY	
53	mophletter <div>Show the field ONLY if: [interventional_yn] = '1'</div>	Please upload approval letter from MoPH for your Interventional Clinical Trial.	file Field Annotation: @HIDDEN @READONLY	
54	irb_amendment	IRB amendment <i>Latest amendment letter (i.e. new name on board)</i>	file Field Annotation: @HIDDEN	
55	irb_application	IRB Application <i>IRB application initial, Related to Binder Study Concept Documents</i>	file	
56	irb_renewal	IRB renewal Application <i>Renewal application for IRB</i>	file Field Annotation: @HIDDEN @READONLY	
57	irb409upload	Upload list of personnel contact, or IRB-409 Research Personnel Form (please do not upload any patient relevant data, some fileds are here to host the empty template):	file Field Annotation: @HIDDEN	
58	binderscreen	Study Activation and Conduct Documents IIC) Subject Screening / Enrollment Lof (All Versions) <i>Related to Binder Category 12</i>	file Field Annotation: @HIDDEN @READONLY	
59	screenform	Subject Screening / Enrollment Log Form <i>Related to Binder Category 13</i>	file Field Annotation: @HIDDEN	
60	closure_report	Study Closure Report (Study closure and Analysis) <i>Closure report</i>	file	
61	logconsent	Subject Informed Consent Log Form (please do not upload any patient relevant data, some fileds are here to host the empty template): <i>Related to Binder Category 15</i>	file Field Annotation: @HIDDEN @READONLY	
62	safetydoc	Study Activation and Conduct Documents IIG) Safety Documents, if applicable <i>Related to Binder Category 18</i>	file Field Annotation: @HIDDEN @READONLY	

63	saereportform	SAE / AE Reporting Form <i>Related to Binder Category 19</i>	file Field Annotation: @HIDDEN @READONLY						
64	other	Other <i>Space for other relevant documents</i>	file Field Annotation: @HIDDEN @READONLY						
65	update_pmo1	PMO Last update	text (date_dmy)						
66	irb_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: <b>Progress Subject Enrollment</b> (progress_subject_enrollment) <div>^ Collapse</div>									
67	recruitment_explain	Please provide here regularly an update about the subject recruitment.	descriptive						
68	enrollment_explain2	You have mentioned that you planning to enroll the following number of subjects: Total: [val_subject_number] If applicable: At Sidra: [val_sidra_subjects1] Outside Sidra: [val_outside_sidra_subject]	descriptive						
69	already_enrolled Show the field ONLY if: [collecting_institute(1)] = '1'	Section Header: Number of subjects already enrolled at Sidra ONLY:	text (number)						
70	cal_already_enrolled	Validation of number input for already enrolled subjects at Sidra only.	calc Calculation: if([already_enrolled]="",0,[already_enrolled]) Field Annotation: @HIDDEN						
71	recruited_parents1 Show the field ONLY if: [collecting_institute(1)] = '1' and ([parentssibbling_collect] = '1' or [parentssibbling_collect] = '2')	Number of already recruited parents / siblings at Sidra ONLY:	text						
72	val_sibling_sidra	Validation of Parents / Siblings at Sidra	calc Calculation: if([recruited_parents1]="",0,[recruited_parents1]) Field Annotation: @HIDDEN						
73	enrolled_outside_sidra Show the field ONLY if: ([collecting_institute(2)] = '1' or [collecting_institute(3)] = '1' or [collecting_institute(4)] = '1' or [collecting_institute(7)] = '1' or [collecting_institute(6)] = '1')	Number of subjects already enrolled OUTSIDE Sidra? <i>a number only, no text</i>	text (number)						
74	val_enrolled_outside_sidra	Validation of subjects already enrolled outside Sidra	calc Calculation: if([enrolled_outside_sidra]="",0,[enrolled_outside_sidra]) Field Annotation: @HIDDEN						
75	recruited_parents2 Show the field ONLY if: [parentssibbling_collect] = '1' and [number_of_subjects_triage(1)] = '1' and ([collecting_institute(2)] = '1' or [collecting_institute(3)] = '1' or [collecting_institute(4)] = '1' or [collecting_institute(7)] = '1' or [collecting_institute(6)] = '1')	Number of already recruited parents / siblings at OUTSIDE Sidra:	text						
76	val_sibling_outside	Validation number siblings /parents outside Sidra	calc Calculation: if([recruited_parents2]="",0,[recruited_parents2]) Field Annotation: @HIDDEN						
77	sum_all_subjects	Sum of all already collected subjects, including parents and siblings	calc Calculation: [cal_already_enrolled]+[val_sibling_sidra]+[val_enrolled_outside_sidra]+[val_sibling_outside]						
78	alter_conditon_check	alter conditon_check	calc Calculation: if ([sum_all_subjects]>[val_subject_number] , 1, 0) Field Annotation: @HIDDEN						

79	b_style_color_red_alert_me Show the field ONLY if: [alter_conditon_check] = '1'	Alert Message: "The number of subjects enrolled exceeds the approved limit. Please adjust the number before submitting this form."	descriptive						
80	plan_currentyear_enroll Show the field ONLY if: [collecting_institute(1)] = '1'	Section Header: How many more subjects you plan to enroll during the current year at Sidra ONLY?	text (number)						
81	cal_this_year_subjects	Validation of number input for subjects planned to be enrolled during the current financial year.	calc Calculation: if([plan_currentyear_enroll]="",0,[plan_currentyear_enroll]) Field Annotation: @HIDDEN						
82	plan_currentyear_enroll_2 Show the field ONLY if: [collecting_institute(2)] = '1' or [collecting_institute(3)] = '1' or [collecting_institute(4)] = '1' or [collecting_institute(7)] = '1' or [collecting_institute(6)] = '1'	How many more subjects you plan to enroll during the current year OUTSIDE Sidra?	text (number)						
83	cal_this_year_subjects_2	Validation of number input for subjects planned to be enrolled during the current financial year from outside Sidra.	calc Calculation: if([plan_currentyear_enroll_2]="",0,[plan_currentyear_enroll_2]) Field Annotation: @HIDDEN						
84	comments_enrollment	Section Header: Space for comments	text						
85	progress_subject_enrollment_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								

Instrument: **Subject Enrollment per SDR# (Umbrella Protocols)** (subject\_enrollment\_per\_sdr\_umbrella\_protocols)[^ Collapse](#)

86	related_sdr	Related SDR# (or sub-activity)	text	
87	total_sub	Total recruited participants under this sub-activity (from start)	text (number)	
88	comment_sub	Comment	text	
89	subject_enrollment_per_sdr_umbrella_protocols_complete	Section Header: <i>Form Status</i>  Complete?	dropdown	
			0	Incomplete
			1	Unverified
			2	Complete

Instrument: **People on IRB** (people\_on\_irb)[^ Collapse](#)

90	explainpersonirb	In this section, you can add people who are mentioned on your IRB protocol. As REDCap cannot pull data from IRBNet automatically, we need your additional input here.	descriptive																		
91	personirb1	Please select the person from the drop-down. In case you cannot find the relevant name please inform researchpmo@sidra.org	sql (autocomplete) <pre>select q1.record,CONCAT(q1.record,' (' ,q1.first_name,' ',q1.last_name,' '))from ( select q.record,max(q.first_name) first_name ,max(q.last_name) last_name from ( select RECORD, case when field_name='first_name' then value end as first_name, case when field_name='last_name' then value end as last_name from redcap.redcap_data where project_id=24 and field_name in ('first_name','last_name') ) q group by q.record) q1</pre>																		
92	role_as_irbnet	Please select the role of the research team member as per IRBNet entry:	dropdown (autocomplete), Required <table><tr><td>7</td><td>Lead Principal Investigator</td></tr><tr><td>1</td><td>Co-Investigator</td></tr><tr><td>2</td><td>Research Coordinator</td></tr><tr><td>3</td><td>Research Project Manager</td></tr><tr><td>4</td><td>Research Nurse</td></tr><tr><td>5</td><td>Data Manager</td></tr><tr><td>6</td><td>Biostatistician</td></tr><tr><td>10</td><td>Other</td></tr><tr><td>11</td><td>Removed from Protocol</td></tr></table>	7	Lead Principal Investigator	1	Co-Investigator	2	Research Coordinator	3	Research Project Manager	4	Research Nurse	5	Data Manager	6	Biostatistician	10	Other	11	Removed from Protocol
7	Lead Principal Investigator																				
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4	Research Nurse																				
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6	Biostatistician																				
10	Other																				
11	Removed from Protocol																				

93	other_role_irbnet  Show the field ONLY if: [role_as_irbnet] = '10'	Please define Other, if selected above.	text																											
94	personirb2	Please select the responsibilities of the person as per IRB Application. <i>LPI by default all granted</i>	<table><tr><td colspan="3">checkbox</td></tr><tr><td>1</td><td>personirb2__1</td><td>Obtain data through communications or interpersonal contact "interaction"</td></tr><tr><td>2</td><td>personirb2__2</td><td>Obtain data through physical procedures or manipulation of the individual or the individual's environment "intervention"</td></tr><tr><td>5</td><td>personirb2__5</td><td>Obtain informed consent</td></tr><tr><td>6</td><td>personirb2__6</td><td>Obtain private identifiable data/samples about human subjects (obtain: record, use, study, or analyze)</td></tr><tr><td>7</td><td>personirb2__7</td><td>Access Subjects medical records</td></tr><tr><td>9</td><td>personirb2__9</td><td>Handling, managing, and processing of samples</td></tr><tr><td>10</td><td>personirb2__10</td><td>Manage and Curate Data in PRIME</td></tr><tr><td>8</td><td>personirb2__8</td><td>Other (please define)</td></tr></table>	checkbox			1	personirb2__1	Obtain data through communications or interpersonal contact "interaction"	2	personirb2__2	Obtain data through physical procedures or manipulation of the individual or the individual's environment "intervention"	5	personirb2__5	Obtain informed consent	6	personirb2__6	Obtain private identifiable data/samples about human subjects (obtain: record, use, study, or analyze)	7	personirb2__7	Access Subjects medical records	9	personirb2__9	Handling, managing, and processing of samples	10	personirb2__10	Manage and Curate Data in PRIME	8	personirb2__8	Other (please define)
checkbox																														
1	personirb2__1	Obtain data through communications or interpersonal contact "interaction"																												
2	personirb2__2	Obtain data through physical procedures or manipulation of the individual or the individual's environment "intervention"																												
5	personirb2__5	Obtain informed consent																												
6	personirb2__6	Obtain private identifiable data/samples about human subjects (obtain: record, use, study, or analyze)																												
7	personirb2__7	Access Subjects medical records																												
9	personirb2__9	Handling, managing, and processing of samples																												
10	personirb2__10	Manage and Curate Data in PRIME																												
8	personirb2__8	Other (please define)																												
95	other_role_irb  Show the field ONLY if: [personirb2(8)] = '1'	Please define Other:	text																											
96	statutuspersionirb	Please select the status of the person's participation.	<table><tr><td colspan="2">dropdown (autocomplete)</td></tr><tr><td>1</td><td>Active on the current approved IRB Protocol</td></tr><tr><td>2</td><td>Was part of the IRB protocol in the past</td></tr><tr><td>3</td><td>Has left Sidra</td></tr><tr><td>4</td><td>Other</td></tr></table> Field Annotation: @HIDDEN	dropdown (autocomplete)		1	Active on the current approved IRB Protocol	2	Was part of the IRB protocol in the past	3	Has left Sidra	4	Other																	
dropdown (autocomplete)																														
1	Active on the current approved IRB Protocol																													
2	Was part of the IRB protocol in the past																													
3	Has left Sidra																													
4	Other																													
97	otherstatusp  Show the field ONLY if: [statutuspersionirb] = '4'	Please define other:	text Field Annotation: @HIDDEN																											
98	personirb3  Show the field ONLY if: [statutuspersionirb] = '4'	Please define others if ticked above.	text Field Annotation: @HIDDEN																											
99	connect_I500_irb	Please select the relevant Research related Conflict of Interest Declaration - L-500A Form.	<table><tr><td colspan="2">sql (autocomplete)</td></tr><tr><td colspan="2">SELECT CONCAT(irb, '(', email, ')('), CASE WHEN sdr IS NULL THEN 'NA' ELSE sdr END, ')') AS I500 FROM (SELECT DISTINCT irb, email, sdr FROM (SELECT MAX(pull_irb_no) AS irb, MAX(emaildropdown) AS email, MAX(auto_sdr) AS sdr FROM (SELECT record, CASE WHEN field_name = 'input_name' THEN value ELSE NULL END AS emaildropdown, CASE WHEN field_name = 'pull_irb_no' THEN value ELSE NULL END AS pull_irb_no, CASE WHEN field_name = 'auto_sdr' THEN value ELSE NULL END AS auto_sdr FROM redcap_data WHERE project_id = '29' AND field_name IN ('input_name', 'auto_sdr', 'pull_irb_no')) a GROUP BY record) a WHERE irb IS NOT NULL) a WHERE email IS NOT NULL ORDER BY 1;</td></tr><tr><td colspan="2">Field Annotation: @HIDDEN</td></tr></table>	sql (autocomplete)		SELECT CONCAT(irb, '(', email, ')('), CASE WHEN sdr IS NULL THEN 'NA' ELSE sdr END, ')') AS I500 FROM (SELECT DISTINCT irb, email, sdr FROM (SELECT MAX(pull_irb_no) AS irb, MAX(emaildropdown) AS email, MAX(auto_sdr) AS sdr FROM (SELECT record, CASE WHEN field_name = 'input_name' THEN value ELSE NULL END AS emaildropdown, CASE WHEN field_name = 'pull_irb_no' THEN value ELSE NULL END AS pull_irb_no, CASE WHEN field_name = 'auto_sdr' THEN value ELSE NULL END AS auto_sdr FROM redcap_data WHERE project_id = '29' AND field_name IN ('input_name', 'auto_sdr', 'pull_irb_no')) a GROUP BY record) a WHERE irb IS NOT NULL) a WHERE email IS NOT NULL ORDER BY 1;		Field Annotation: @HIDDEN																						
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SELECT CONCAT(irb, '(', email, ')('), CASE WHEN sdr IS NULL THEN 'NA' ELSE sdr END, ')') AS I500 FROM (SELECT DISTINCT irb, email, sdr FROM (SELECT MAX(pull_irb_no) AS irb, MAX(emaildropdown) AS email, MAX(auto_sdr) AS sdr FROM (SELECT record, CASE WHEN field_name = 'input_name' THEN value ELSE NULL END AS emaildropdown, CASE WHEN field_name = 'pull_irb_no' THEN value ELSE NULL END AS pull_irb_no, CASE WHEN field_name = 'auto_sdr' THEN value ELSE NULL END AS auto_sdr FROM redcap_data WHERE project_id = '29' AND field_name IN ('input_name', 'auto_sdr', 'pull_irb_no')) a GROUP BY record) a WHERE irb IS NOT NULL) a WHERE email IS NOT NULL ORDER BY 1;																														
Field Annotation: @HIDDEN																														



100	<div>addedtoexempt</div> <div>Show the field ONLY if: [protocol_type] = '1'</div>	<div>Section Header:</div> <div>In case of an "Exempt" Protocol: The number of People mentioned at the beginning of IRB submission might vary of the people working on it later. If that person joins later - no re-submission of documents to the IRB office is necessary. In this case, please add the person here to document it properly. The LPI has the responsibility to keep track, who is working on that protocol, and has to ensure valid training and certificates (e.g. CITI) are in place.</div> <div>If you add a person under these circumstances, then please click "Yes". Otherwise keep blank or click Not Applicable.</div>	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>Not Applicable</td></tr></table>	1	Yes	2	Not Applicable
1	Yes						
2	Not Applicable						
101	<div>how_submit_prime_access</div>	<div>Section Header:</div> <div>Once you have selected the Prime Access Role, and you are sure that you would like to submit the access to prime, please go tot the Instrument access to Prime and submit your request. Changes you can also request in that instrument.</div>	<div>radio</div> <table><tr><td>1</td><td>Click here to see more Information</td></tr><tr><td>2</td><td>Don't need more info</td></tr></table>	1	Click here to see more Information	2	Don't need more info
1	Click here to see more Information						
2	Don't need more info						
102	<div>info_prime_res_enrol</div> <div>Show the field ONLY if: [how_submit_prime_access] = '1'</div>	<div>Please note: as a minimum requirement, in order to have access in Prime in the Role as "Research Enrollment" it is necessary to have the following Responsibilities clicked in the IRB Application:- Obtain data through communication or interpersonal contact "interaction" - Obtain informed consent - Obtain private identifiable data/samples about human subjects (Obtain: record, use, study, or analyze) - Access Subjects medical records And mention under "Others", the following text, beside other text you might have entered:"Manage and curate data in PRIME, handle and manage samples "</div>	<div>descriptive</div>				
103	<div>info_prime_clinical_data</div> <div>Show the field ONLY if: [how_submit_prime_access] = '1'</div>	<div>Please note: as a minimum requirement, in order to have access in Prime in the Role as "Clinical Data Manager" it is necessary to have the following Responsibilities clicked in the IRB Application:- Obtain private identifiable data/samples about human subjects (Obtain: record, use, study, or analyze)- Access Subjects medical recordsAnd mention under "Others", the following text, beside other text you might have entered: "Manage and curate data in PRIME, handle and manage samples"</div>	<div>descriptive</div>				
104	<div>info_prime_sample</div> <div>Show the field ONLY if: [how_submit_prime_access] = '1'</div>	<div>Please note: as a minimum requirement, in order to have access in Prime in the Role as "Sample (Lab) inventory" it is necessary to state under "Other" responsibilities the following:"Manage and curate data in PRIME related to sample inventory, create sample ID, handle, process, and manage samples "</div>	<div>descriptive</div>				
105	<div>infor_prime_project_info</div> <div>Show the field ONLY if: [how_submit_prime_access] = '1'</div>	<div>Please note: as a minimum requirement, in order to have access in Prime in the Role as "Project Info" it is necessary to state under "Other" responsibilities the following:"Manage and curate data in PRIME"</div>	<div>descriptive</div>				
106	<div>redcap_regstry</div>	<div>Section Header:</div> <div>Access for a REDCap based tool to collect patient data</div>	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table>	1	Yes	2	No
1	Yes						
2	No						
107	<div>pmo_approval</div> <div>Show the field ONLY if: [add_prime_approval] = '1'</div>	<div>Section Header: <i>Below use for PMO ONLY</i></div> <div>Approved for PRIME / (REDCap Patient data)</div>	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table>	1	Yes	2	No
1	Yes						
2	No						
108	<div>prime_ok_expiry</div> <div>Show the field ONLY if: [pmo_approval] = '1'</div>	<div>Approval will expire on:current IRB approval until: [expiry_date_2]</div>	<div>text (date_dmy)</div> <div>Field Annotation: @DEFAULT=[expiry_date_2]</div>				
109	<div>note_prime_yes</div> <div>Show the field ONLY if: [pmo_approval] = '1'</div>	<div>Approved by PMO to be used in PRIME</div>	<div>descriptive</div>				

110	<div>please_select_the_responsi</div> <div>Show the field ONLY if: [pmo_approval] = '1'</div>	Please select the responsibilities of the person as per PRIME Access Request (tick all that apply)	<div>checkbox</div> <table><tr><td>1</td><td>please_select_the_responsi__1</td><td>Clinical Research Coordinator (CRC)</td></tr><tr><td>2</td><td>please_select_the_responsi__2</td><td>Clinical Data Manager</td></tr><tr><td>3</td><td>please_select_the_responsi__3</td><td>Sample/Lab Manager</td></tr><tr><td>4</td><td>please_select_the_responsi__4</td><td>Report Manager</td></tr><tr><td>5</td><td>please_select_the_responsi__5</td><td>Metadata Manager</td></tr><tr><td>6</td><td>please_select_the_responsi__6</td><td>PHI Data Manager</td></tr><tr><td>7</td><td>please_select_the_responsi__7</td><td>PHI Data Reader</td></tr><tr><td>8</td><td>please_select_the_responsi__8</td><td>PHI Reports</td></tr></table>	1	please_select_the_responsi__1	Clinical Research Coordinator (CRC)	2	please_select_the_responsi__2	Clinical Data Manager	3	please_select_the_responsi__3	Sample/Lab Manager	4	please_select_the_responsi__4	Report Manager	5	please_select_the_responsi__5	Metadata Manager	6	please_select_the_responsi__6	PHI Data Manager	7	please_select_the_responsi__7	PHI Data Reader	8	please_select_the_responsi__8	PHI Reports
1	please_select_the_responsi__1	Clinical Research Coordinator (CRC)																									
2	please_select_the_responsi__2	Clinical Data Manager																									
3	please_select_the_responsi__3	Sample/Lab Manager																									
4	please_select_the_responsi__4	Report Manager																									
5	please_select_the_responsi__5	Metadata Manager																									
6	please_select_the_responsi__6	PHI Data Manager																									
7	please_select_the_responsi__7	PHI Data Reader																									
8	please_select_the_responsi__8	PHI Reports																									
111	<div>access_request_to_prime</div> <div>Show the field ONLY if: [pmo_approval] = '1' or [pmo_approval] = '2'</div>	Access Request to PRIME	descriptive																								
112	<div>request_prime_access</div> <div>Show the field ONLY if: [pmo_approval] = '1' and ([personirb2(10)] = '1' or [personirb2(9)] = '1' or [personirb2(7)] = '1' or [personirb2(6)] = '1' or [personirb2(5)] = '1' or [personirb2(1)] = '1')</div>	Research Enrollment	descriptive																								
113	<div>research_enrollment_val</div>	Research Enrollment value	calc Calculation: if((( [pmo_approval] = '1' and ([personirb2(10)] = '1' or [personirb2(9)] = '1' or [personirb2(7)] = '1' or [personirb2(6)] = '1' or [personirb2(5)] = '1' or [personirb2(1)] = '1')) = 1, 1, 0)																								
114	<div>request_prime_access_2</div> <div>Show the field ONLY if: [pmo_approval] = '1' and ([personirb2(10)] = '1' or [personirb2(9)] = '1' or [personirb2(7)] = '1' or [personirb2(6)] = '1')</div>	Clinical Data Manager	descriptive																								
115	<div>clinical_data_manager_valu</div>	Clinical Data Manager value	calc Calculation: if((( [pmo_approval] = '1' and ([personirb2(10)] = '1' or [personirb2(9)] = '1' or [personirb2(7)] = '1' or [personirb2(6)] = '1')) = 1, 1, 0)																								
116	<div>request_prime_access_3</div> <div>Show the field ONLY if: [pmo_approval] = '1' and ([personirb2(9)] = '1' or [personirb2(10)] = '1')</div>	Sample (Lab) Inventory	descriptive																								
117	<div>sample_lab_inventory_val</div>	Sample (Lab) Inventory value	calc Calculation: if((( [pmo_approval] = '1' and ([personirb2(9)] = '1' or [personirb2(10)] = '1')) = 1, 1, 0)																								
118	<div>request_prime_access_4</div> <div>Show the field ONLY if: [pmo_approval] = '1' and ([personirb2(10)] = '1')</div>	Project Info	descriptive																								
119	<div>project_info_value</div>	Project Info value	calc Calculation: if((( [pmo_approval] = '1' and ([personirb2(10)] = '1')) = 1, 1, 0)																								
120	<div>request_prime_access_5</div> <div>Show the field ONLY if: [pmo_approval] = '2'</div>	No Access to PRIME needed	descriptive																								
121	<div>comments_person</div>	Section Header: Space for comments	text Field Annotation: @CHARLIMIT=250																								
122	<div>update_pmo2</div>	Section Header: PMO last update	text (date_dmy)																								

123	date_diff	Days until expiry	calc Calculation: datediff([prime_ok_expiry],'today','d') Field Annotation: @READONLY								
124	people_on_irb_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete		
0	Incomplete										
1	Unverified										
2	Complete										
Instrument: <b>Dependent IRB's</b> (dependent_irbs) <a href="#">^ Collapse</a>											
125	explain_dependent	If you are working with samples or data from other Institutions, you need an IRB approval at the Institution where the samples got collected, and additionally an approval from the Sidra IRB. However, the IRB from the original Institution needs eventually to be renewed annually. Here you can upload documents for IRB's on which the Sidra IRB would depend on. And create a reminder so you don't forget to initiate the IRB renewal at the collaborating Institution, if needed.	descriptive								
126	coll_irb_number	IRB number of the IRB approval from the collaborating institution.	text								
127	coll_irbtype	Type of IRB at collaborating Institution:	dropdown (autocomplete) <table border="1"> <tr><td>1</td><td>Exempt</td></tr> <tr><td>2</td><td>Expedited</td></tr> <tr><td>3</td><td>Full Board</td></tr> <tr><td>10</td><td>Other</td></tr> </table>	1	Exempt	2	Expedited	3	Full Board	10	Other
1	Exempt										
2	Expedited										
3	Full Board										
10	Other										
128	renewal_collirb	Does it need a renewal?	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No				
1	Yes										
0	No										
129	date_coll_expire	Enter the expiry date of the IRB from the collaborating institution, on which the Sidra IRB depends on.	text (date_dmy)								
130	approval_letter_coll	Upload Approval letter (from collaborating Institution)	file								
131	appl_coll	Upload IRB application document for collaborating Institution.	file								
132	upload_more	Space to upload additional documents	file								
133	comment_coll	Comments	text								
134	dependent_irbs_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete		
0	Incomplete										
1	Unverified										
2	Complete										
Instrument: <b>Consent Checklist</b> (consent_checklist) <a href="#">^ Collapse</a>											
135	template	Section Header: <i>Checklist for all Mandatory parts as per IRB Template</i> The content was copied from a template for:	radio <table border="1"> <tr><td>1</td><td>IRB-400 Informed Consent Form -English</td></tr> <tr><td>2</td><td>IRB-402 Parental Permission Form -English</td></tr> </table>	1	IRB-400 Informed Consent Form -English	2	IRB-402 Parental Permission Form -English				
1	IRB-400 Informed Consent Form -English										
2	IRB-402 Parental Permission Form -English										
136	consent_from_version	Consent from Version for this study.	text								
137	form_approval_date	Approval date for this form	text (date_dmy)								
138	intro	Section Header: Does the form include Introduction?	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No				
1	Yes										
0	No										
139	background	Does the form include Background & Purpose?	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No				
1	Yes										
0	No										
140	number_of_subjects_q	Does the form include number of subjects?	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No				
1	Yes										
0	No										
141	text_number_of_subjects Show the field ONLY if: [number_of_subjects_q] = '1'	Provide the text for number of subjects	notes								

142	duration	Does the form mentioned the study duration and length of participation?	yesno 1 Yes 0 No
143	duration_details Show the field ONLY if: [duration] = '1'	Provide the text for study duration and length of participation	notes
144	procedure	Does the form include and describe the planned Procedures and if applicable details for the Processing samples?	yesno 1 Yes 0 No
145	bad Show the field ONLY if: [procedure] = '0'		descriptive
146	tesxtp Show the field ONLY if: [procedure] = '1'	Provide text from the form about Procedure, Processing	notes
147	alternative	Does the form include information about Alternative Procedure?	yesno 1 Yes 0 No
148	text_a Show the field ONLY if: [alternative] = '1'	Provide the text from the form about the Alternative Procedure	notes
149	side	Does the form includes information about risks and side effects ?	yesno 1 Yes 0 No
150	risk Show the field ONLY if: [side] = '1'	Provide the text in the form about (Risks, Side Effects and/or Discomforts)	notes
151	unforeseen	Does the form include information about Unforeseen Risks?	yesno 1 Yes 0 No
152	textu Show the field ONLY if: [unforeseen] = '1'	Provide the text from the form about Unforeseen Risks	notes
153	pregnancy	Does the form mentioned any thing about pregnancy (if applicable)?	yesno 1 Yes 0 No
154	textp Show the field ONLY if: [pregnancy] = '1'	Provide text from the form about pregnancy	notes
155	new_finding	Does the form mentioned anything about New Findings and its affect on participants?	yesno 1 Yes 0 No
156	textn Show the field ONLY if: [new_finding] = '1'	Provide text from the form about New Findings	notes
157	results	Does the form mentioned anything regarding feedback to the participant of results from the research tests/surveys?	yesno 1 Yes 0 No
158	textr Show the field ONLY if: [results] = '1'	Provide text from the form about participant research results or surveys	notes
159	benefits_from_study	Does the form include a section about the benefits to the participant of the study?	yesno 1 Yes 0 No

160	specify_benefits Show the field ONLY if: [benefits_from_study] = '1'	Provide text from the form about the benefits	notes
161	cost	Does the form include information regarding the cost of participating in the study?	yesno 1 Yes 0 No
162	textc Show the field ONLY if: [cost] = '1'	Provide text from the form about the cost	notes
163	compensation_planned	Does the form include a section about compensation for the study?	radio 1 Information yes, but no compensation 2 Information and compensation will be provided 3 Not included / not applicable
164	specify_compensation Show the field ONLY if: [compensation_planned] = '1' or [compensation_planned] = '2'	Provide text from the form about compensation	notes
165	injuries	Does the form include information about Research Related Injuries?	yesno 1 Yes 0 No
166	texti Show the field ONLY if: [injuries] = '1'	Provide text from the form about Research Related Injuries	notes
167	confidentiality	Does the form include information about participant data confidentiality?	yesno 1 Yes 0 No
168	textd Show the field ONLY if: [confidentiality] = '1'	Provide text from the form regarding data confidentiality	notes
169	gain	Does the form include any information about Commercial Gain (if applicable)	radio 1 Yes 0 No 2 Not Applicable
170	textg Show the field ONLY if: [gain] = '1'	Provide text from the form about Commercial Gain	notes
171	team	Does the form include information about Research Team Contact?	yesno 1 Yes 0 No
172	textt Show the field ONLY if: [team] = '1'	Provide text from the form about Research Team Contact	notes
173	irb_contact	Does the from include information about IRB Office Contact?	yesno 1 Yes 0 No
174	textirb Show the field ONLY if: [irb_contact] = '1'	Provide text from the form about IRB Contact	notes
175	voluntary	Does the form include information about Voluntary Participation/Withdrawal?	yesno 1 Yes 0 No
176	textv Show the field ONLY if: [voluntary] = '1'	Provide text from the form about Voluntary Participation/Withdrawal	notes

177	future1	Does the form include information about storing and sharing a participant information or samples for future use ?	yesno 1 Yes 0 No
178	textf Show the field ONLY if: [future1] = '1'	Provide text from the form about Storing and Sharing Your Information or Samples for Future Use	notes
179	storage	Does the study provide information about place and duration of storage of information or samples?	radio 1 Yes, no restrictions 2 Yes, with restrictions 3 Not included
180	place_storage Show the field ONLY if: [storage] = '1' or [storage] = '2'	Provide text from the form about the place & duration of storage of information or samples	notes
181	future2	Does the form include information about withdrawal of a participant information or samples from future use (include if applicable)	yesno 1 Yes 0 No
182	textw Show the field ONLY if: [future2] = '1'	Provide text from the form about Withdrawal of Your Information or Samples from Future Use (include if applicable)	notes
183	recipient	Does the form include information about providing information or samples to recipient researchers (include if applicable)	yesno 1 Yes 0 No
184	textff Show the field ONLY if: [recipient] = '1'	Provide text from the form about providing information or samples to recipient researchers	notes
185	future_study_use	Does the form includes a separate consent for optional future use?	radio 1 Yes, separate field for Signature 2 Yes, covered by overall consent signature 3 Not included (but planned) 4 Not included (not planned / not applicable)
186	text_future_use Show the field ONLY if: [future_study_use] = '1' or [future_study_use] = '2'	Provide text from the form about optional future use	notes
187	future_use_different_topic	Does the form include consent to contact a participant to participate in future studies (include if applicable)	radio 1 Yes, separate field for Signature 2 Yes, covered by overall consent signature 4 Not included (not planned / not applicable)
188	text_future_different Show the field ONLY if: [future_use_different_topic] = '1' or [future_use_different_topic] = '2'	Provide text from the form about contacting a participant to participate in future studies (include if applicable)	notes
189	consent_part	Provide the text of the overall consent part from the consent form:	notes
190	visit_schedule	Section Header: <i>Procedure Details</i> How many visits will the patient need?	checkbox 1 visit_schedule__1 Only once to take consent 2 visit_schedule__2 During regular clinical visit(s) or follow up 3 visit_schedule__3 Extra visit(s) for research purposes 4 visit_schedule__4 No visit(s) needed 10 visit_schedule__10 Other
191	other_follow_up_visit Show the field ONLY if: [visit_schedule(10)] = '1'	Please explain details about "Other" for follow up visits	notes

192	study_will_involve	Your study will involve	<div>checkbox</div> <table><tr><td>1</td><td>study_will_involve__1</td><td>Sample Collection</td></tr><tr><td>2</td><td>study_will_involve__2</td><td>Questionnaire</td></tr><tr><td>3</td><td>study_will_involve__3</td><td>Patient Health Data and History</td></tr><tr><td>4</td><td>study_will_involve__4</td><td>Provide medication</td></tr><tr><td>5</td><td>study_will_involve__5</td><td>Apply tests and / or procedures</td></tr><tr><td>19</td><td>study_will_involve__19</td><td>Others</td></tr><tr><td>20</td><td>study_will_involve__20</td><td>Not Applicable</td></tr></table>	1	study_will_involve__1	Sample Collection	2	study_will_involve__2	Questionnaire	3	study_will_involve__3	Patient Health Data and History	4	study_will_involve__4	Provide medication	5	study_will_involve__5	Apply tests and / or procedures	19	study_will_involve__19	Others	20	study_will_involve__20	Not Applicable																																										
1	study_will_involve__1	Sample Collection																																																																
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19	study_will_involve__19	Others																																																																
20	study_will_involve__20	Not Applicable																																																																
193	study_involve_other Show the field ONLY if: [study_will_involve(19)] = '1'	Define Other	text																																																															
194	sample_kind_2 Show the field ONLY if: [study_will_involve(1)] = '1'	Sample type collections <i>click what applies</i>	<div>checkbox</div> <table><tr><td>1</td><td>sample_kind_2__1</td><td>Whole blood</td></tr><tr><td>2</td><td>sample_kind_2__2</td><td>Saliva</td></tr><tr><td>3</td><td>sample_kind_2__3</td><td>Stool</td></tr><tr><td>4</td><td>sample_kind_2__4</td><td>Urine</td></tr><tr><td>5</td><td>sample_kind_2__5</td><td>Left over tissue samples from pathology</td></tr><tr><td>6</td><td>sample_kind_2__6</td><td>Placental tissue</td></tr><tr><td>7</td><td>sample_kind_2__7</td><td>Left over Biopsy</td></tr><tr><td>8</td><td>sample_kind_2__8</td><td>Skin swab</td></tr><tr><td>9</td><td>sample_kind_2__9</td><td>Buccal swab</td></tr><tr><td>10</td><td>sample_kind_2__10</td><td>Amniotic fluid</td></tr><tr><td>11</td><td>sample_kind_2__11</td><td>Cord blood</td></tr><tr><td>12</td><td>sample_kind_2__12</td><td>Breast milk</td></tr><tr><td>13</td><td>sample_kind_2__13</td><td>Vaginal swab</td></tr><tr><td>14</td><td>sample_kind_2__14</td><td>Left over stool</td></tr><tr><td>15</td><td>sample_kind_2__15</td><td>Left over plasma</td></tr><tr><td>16</td><td>sample_kind_2__16</td><td>Left over microbial DNA from stool</td></tr><tr><td>17</td><td>sample_kind_2__17</td><td>Follicular fluid</td></tr><tr><td>18</td><td>sample_kind_2__18</td><td>Endometrial tissue</td></tr><tr><td>19</td><td>sample_kind_2__19</td><td>Left over CSF</td></tr><tr><td>20</td><td>sample_kind_2__20</td><td>Nail clippings</td></tr><tr><td>50</td><td>sample_kind_2__50</td><td>Other</td></tr></table>	1	sample_kind_2__1	Whole blood	2	sample_kind_2__2	Saliva	3	sample_kind_2__3	Stool	4	sample_kind_2__4	Urine	5	sample_kind_2__5	Left over tissue samples from pathology	6	sample_kind_2__6	Placental tissue	7	sample_kind_2__7	Left over Biopsy	8	sample_kind_2__8	Skin swab	9	sample_kind_2__9	Buccal swab	10	sample_kind_2__10	Amniotic fluid	11	sample_kind_2__11	Cord blood	12	sample_kind_2__12	Breast milk	13	sample_kind_2__13	Vaginal swab	14	sample_kind_2__14	Left over stool	15	sample_kind_2__15	Left over plasma	16	sample_kind_2__16	Left over microbial DNA from stool	17	sample_kind_2__17	Follicular fluid	18	sample_kind_2__18	Endometrial tissue	19	sample_kind_2__19	Left over CSF	20	sample_kind_2__20	Nail clippings	50	sample_kind_2__50	Other
1	sample_kind_2__1	Whole blood																																																																
2	sample_kind_2__2	Saliva																																																																
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20	sample_kind_2__20	Nail clippings																																																																
50	sample_kind_2__50	Other																																																																
195	blood_details Show the field ONLY if: [sample_kind_2(1)] = '1'	Blood Details	notes																																																															
196	saliva Show the field ONLY if: [sample_kind_2(2)] = '1'	Saliva Details	notes																																																															
197	stool Show the field ONLY if: [sample_kind_2(3)] = '1'	Stool Details	notes																																																															
198	urine_details Show the field ONLY if: [sample_kind_2(4)] = '1'	Urine Details	notes																																																															
199	left_over Show the field ONLY if: [sample_kind_2(5)] = '1'	Left over tissue samples from pathology Details	notes																																																															
200	tissue_details Show the field ONLY if: [sample_kind_2(6)] = '1'	Tissue Details	notes																																																															

201	biopsy Show the field ONLY if: [sample_kind_2(7)] = '1'	Biopsy details	notes																																
202	skin_swab_detail Show the field ONLY if: [sample_kind_2(8)] = '1'	Skin Swab details	notes																																
203	buccal_swab_detail Show the field ONLY if: [sample_kind_2(9)] = '1'	Buccal Swab detail	notes																																
204	other_sample Show the field ONLY if: [sample_kind_2(50)] = '1'	If other, please specify	notes																																
205	questionnaire_like Show the field ONLY if: [study_will_involve(2)] = '1'	Questionnaire-like <i>click what applies</i>	<table><tr><td colspan="3">checkbox</td></tr><tr><td>1</td><td>questionnaire_like__1</td><td>Demographic and family information</td></tr><tr><td>2</td><td>questionnaire_like__2</td><td>Questionnaire environmental, physical and mental health</td></tr><tr><td>3</td><td>questionnaire_like__3</td><td>Dietary and smoking habits</td></tr><tr><td>4</td><td>questionnaire_like__4</td><td>Interview</td></tr><tr><td>5</td><td>questionnaire_like__5</td><td>Other</td></tr></table>			checkbox			1	questionnaire_like__1	Demographic and family information	2	questionnaire_like__2	Questionnaire environmental, physical and mental health	3	questionnaire_like__3	Dietary and smoking habits	4	questionnaire_like__4	Interview	5	questionnaire_like__5	Other												
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3	questionnaire_like__3	Dietary and smoking habits																																	
4	questionnaire_like__4	Interview																																	
5	questionnaire_like__5	Other																																	
206	q1 Show the field ONLY if: [questionnaire_like(1)] = '1'	Please Upload the questionnaire	file																																
207	q2 Show the field ONLY if: [questionnaire_like(2)] = '1'	Please Upload the questionnaire	file																																
208	q3 Show the field ONLY if: [questionnaire_like(3)] = '1'	Please Upload the questionnaire	file																																
209	q4 Show the field ONLY if: [questionnaire_like(4)] = '1'	Please Upload the interview questions	file																																
210	q5 Show the field ONLY if: [questionnaire_like(5)] = '1'	Please specify	notes																																
211	q6 Show the field ONLY if: [questionnaire_like(5)] = '1'	Please Upload	file																																
212	health_data	Patient Health Data and History <i>click what applies</i>	<table><tr><td colspan="3">checkbox</td></tr><tr><td>1</td><td>health_data__1</td><td>Vital Signs (blood pressure, pulse, temperature, oxygen saturation, height &amp; weight)</td></tr><tr><td>3</td><td>health_data__3</td><td>Pregnancy Information</td></tr><tr><td>4</td><td>health_data__4</td><td>Disease History</td></tr><tr><td>5</td><td>health_data__5</td><td>Any previous surgical interventions</td></tr><tr><td>6</td><td>health_data__6</td><td>Medication history/current</td></tr><tr><td>7</td><td>health_data__7</td><td>Genetic information</td></tr><tr><td>8</td><td>health_data__8</td><td>Results of tests and/or images (such as X-rays and MRI)</td></tr><tr><td>9</td><td>health_data__9</td><td>Medical records from Cerner</td></tr><tr><td>50</td><td>health_data__50</td><td>Other</td></tr></table>			checkbox			1	health_data__1	Vital Signs (blood pressure, pulse, temperature, oxygen saturation, height & weight)	3	health_data__3	Pregnancy Information	4	health_data__4	Disease History	5	health_data__5	Any previous surgical interventions	6	health_data__6	Medication history/current	7	health_data__7	Genetic information	8	health_data__8	Results of tests and/or images (such as X-rays and MRI)	9	health_data__9	Medical records from Cerner	50	health_data__50	Other
checkbox																																			
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9	health_data__9	Medical records from Cerner																																	
50	health_data__50	Other																																	
213	health_data_text	Please provide text asking for permission accessing Health data	notes Field Annotation: @HIDDEN																																



214	genom	Does the form include consent for the participants genomic sequencing?	radio <table><tr><td>1</td><td>Not applicable</td></tr><tr><td>2</td><td>Yes, participant needs to consent specifically for it</td></tr><tr><td>3</td><td>Yes, its mentioned in the form, and covered by the overall consent</td></tr><tr><td>4</td><td>Not mentioned in the form, but planned to do so</td></tr></table>	1	Not applicable	2	Yes, participant needs to consent specifically for it	3	Yes, its mentioned in the form, and covered by the overall consent	4	Not mentioned in the form, but planned to do so
1	Not applicable										
2	Yes, participant needs to consent specifically for it										
3	Yes, its mentioned in the form, and covered by the overall consent										
4	Not mentioned in the form, but planned to do so										
215	genomic_sequencing Show the field ONLY if: [genom] = '2' or [genom] = '3'	Please provide text for genomic sequencing	notes								
216	cellline	Does the form include the consent to create cell-lines from obtained materials	radio <table><tr><td>1</td><td>Not included in the form/ not applicable</td></tr><tr><td>2</td><td>Yes, participant needs to consent specifically for it</td></tr><tr><td>3</td><td>Yes, its mentioned in the form, and covered by the overall consent</td></tr></table>	1	Not included in the form/ not applicable	2	Yes, participant needs to consent specifically for it	3	Yes, its mentioned in the form, and covered by the overall consent		
1	Not included in the form/ not applicable										
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3	Yes, its mentioned in the form, and covered by the overall consent										
217	cell_text Show the field ONLY if: [cellline] = '2' or [cellline] = '3'	Please provide text for cell-line creation	notes								
218	germline	Does the form include the consent to allow for germ-line genetics	radio <table><tr><td>1</td><td>Not included in the form/ not applicable</td></tr><tr><td>2</td><td>Yes, participant needs to consent specifically for it</td></tr><tr><td>3</td><td>Yes, its mentioned in the form, and covered by the overall consent</td></tr></table>	1	Not included in the form/ not applicable	2	Yes, participant needs to consent specifically for it	3	Yes, its mentioned in the form, and covered by the overall consent		
1	Not included in the form/ not applicable										
2	Yes, participant needs to consent specifically for it										
3	Yes, its mentioned in the form, and covered by the overall consent										
219	gl_text Show the field ONLY if: [germline] = '2' or [germline] = '3'	Please provide specific text for germ-line	notes								
220	communicate_outcomes	Does the form include a section to give permission to be contacted for outcomes which may be found during the research?	radio <table><tr><td>1</td><td>Not included in the form / not applicable</td></tr><tr><td>2</td><td>Yes, participant needs to consent specifically for it</td></tr><tr><td>3</td><td>Yes, it's mentioned in the form, and covered by overall consent</td></tr></table>	1	Not included in the form / not applicable	2	Yes, participant needs to consent specifically for it	3	Yes, it's mentioned in the form, and covered by overall consent		
1	Not included in the form / not applicable										
2	Yes, participant needs to consent specifically for it										
3	Yes, it's mentioned in the form, and covered by overall consent										
221	text_outcome_contact Show the field ONLY if: [communicate_outcomes] = '2' or [communicate_outcome s] = '3'	Provide text from the form about being contacted with specific research outcomes.	notes								
222	research_method	Does the form explicit ask for permission of samples and data to be used in Research outside the scope of this study, i.e. unrelated research fields, in the future?	radio <table><tr><td>1</td><td>Not applicable</td></tr><tr><td>2</td><td>Yes, it's mentioned in the form, and covered by overall consent</td></tr><tr><td>3</td><td>Yes, participant needs to consent specifically for it</td></tr></table>	1	Not applicable	2	Yes, it's mentioned in the form, and covered by overall consent	3	Yes, participant needs to consent specifically for it		
1	Not applicable										
2	Yes, it's mentioned in the form, and covered by overall consent										
3	Yes, participant needs to consent specifically for it										
223	explicit_other_field Show the field ONLY if: [research_method] = '3' or [re search_method] = '2'	Provide Text details	notes								
224	comment_consent_check	Comment	text								
225	upload_the_consent_form	Upload the consent form	file								
226	extra_genomics	consent specifically for genomic sequencing	calc Calculation: if([genom]=2,1,0)								
227	cell_line_extra	consent specifically to create cell line	calc Calculation: if([cellline]=2,1,0)								
228	extra_germline	consent specifically for germ-line genetics	calc Calculation: if([germline]=2,1,0)								
229	extra_contacted	consent to be contacted for findings	calc Calculation: if([communicate_outcomes]=2,1,0)								

230	explicit_other_research	explicit consent to use samples and data outside the research scope of the current study	calc Calculation: if([research_method]=3,1,0)								
231	latest_edit_by_pmo	Latest Edit by PMO	text (date_dmy)								
232	consent_checklist_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete		
0	Incomplete										
1	Unverified										
2	Complete										
Instrument: <b>Consent Form MetaData</b> (consent_form_metadata) <div>^ Collapse</div>											
233	consent_options	CONSENT OPTIONS	descriptive								
234	consent_form_waiver	Consent Form Waiver	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
235	off_protocol_use	Off-Protocol sample use	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										
236	basic_research	Basic research	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										
237	followup_contact	Follow-up contact for other studies	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										
238	contact_for_similar_studie	Contact for similar studies	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										
239	cell_line_creation	Cell-line creation	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										
240	germ_line_genetics	Germ-line genetics	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										
241	store_future_use	Store and share sample for future use	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										
242	store_use_information	Store and share information for future use	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										

243	followup_visits_samples	Follow-up visits for giving samples	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										
244	incidental_findings	Incidental findings	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										
245	sampling_type_options	SAMPLING TYPE OPTIONS	descriptive								
246	whole_blood_sampling_type	Whole blood	dropdown (autocomplete) <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Optional</td></tr></table>	1	Yes	2	No	3	Optional		
1	Yes										
2	No										
3	Optional										
247	saliva_sampling_type	Saliva	dropdown (autocomplete) <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Optional</td></tr></table>	1	Yes	2	No	3	Optional		
1	Yes										
2	No										
3	Optional										
248	stool_sampling_type	Stool	dropdown (autocomplete) <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Optional</td></tr></table>	1	Yes	2	No	3	Optional		
1	Yes										
2	No										
3	Optional										
249	urine_sampling_type	Urine	dropdown (autocomplete) <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Optional</td></tr></table>	1	Yes	2	No	3	Optional		
1	Yes										
2	No										
3	Optional										
250	left_over_tissue_samples_sam pling_type	Left over tissue samples from pathology	dropdown (autocomplete) <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Optional</td></tr></table>	1	Yes	2	No	3	Optional		
1	Yes										
2	No										
3	Optional										
251	left_over_biopsy_sampling_typ e	Left over Biopsy	dropdown (autocomplete) <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Optional</td></tr></table>	1	Yes	2	No	3	Optional		
1	Yes										
2	No										
3	Optional										
252	skin_swab_sampling_type	Skin swab	dropdown (autocomplete) <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Optional</td></tr></table>	1	Yes	2	No	3	Optional		
1	Yes										
2	No										
3	Optional										
253	buccal_swab_sampling_type	Buccal swab	dropdown (autocomplete) <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Optional</td></tr></table>	1	Yes	2	No	3	Optional		
1	Yes										
2	No										
3	Optional										
254	placental_tissue_sampling_typ e	Placental tissue	dropdown (autocomplete) <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Optional</td></tr></table>	1	Yes	2	No	3	Optional		
1	Yes										
2	No										
3	Optional										
255	amniotic_fluid_sampling_type	Amniotic fluid	dropdown (autocomplete) <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Optional</td></tr></table>	1	Yes	2	No	3	Optional		
1	Yes										
2	No										
3	Optional										

256	cord_blood_sampling_type	Cord blood	dropdown (autocomplete) <div><div>1 Yes</div><div>2 No</div><div>3 Optional</div></div>
257	breast_milk_sampling_type	Breast milk	dropdown (autocomplete) <div><div>1 Yes</div><div>2 No</div><div>3 Optional</div></div>
258	vaginal_swab_sampling_type	Vaginal swab	dropdown (autocomplete) <div><div>1 Yes</div><div>2 No</div><div>3 Optional</div></div>
259	left_over_stool_sampling_type	Left over stool	dropdown (autocomplete) <div><div>1 Yes</div><div>2 No</div><div>3 Optional</div></div>
260	left_over_plasma_sampling_type	Left over plasma	dropdown (autocomplete) <div><div>1 Yes</div><div>2 No</div><div>3 Optional</div></div>
261	left_over_microbial_dna_sampling_type	Left over microbial DNA from stool	dropdown (autocomplete) <div><div>1 Yes</div><div>2 No</div><div>3 Optional</div></div>
262	follicular_fluid_sampling_type	Follicular fluid	dropdown (autocomplete) <div><div>1 Yes</div><div>2 No</div><div>3 Optional</div></div>
263	endometrial_tissue_sampling_type	Endometrial tissue	dropdown (autocomplete) <div><div>1 Yes</div><div>2 No</div><div>3 Optional</div></div>
264	left_over_csf	Left over CSF	dropdown (autocomplete) <div><div>1 Yes</div><div>2 No</div><div>3 Optional</div></div>
265	nail_clippings_sampling_type	Nail clippings	dropdown (autocomplete) <div><div>1 Yes</div><div>2 No</div><div>3 Optional</div></div>
266	donating_samples_blood	Donating samples-blood	dropdown (autocomplete) <div><div>1 On</div><div>2 Off</div><div>3 Option</div><div>4 Not Applicable</div></div> <div>Field Annotation: @HIDDEN</div>
267	donating_samples_stool	Donating samples-stool	dropdown (autocomplete) <div><div>1 On</div><div>2 Off</div><div>3 Option</div><div>4 Not Applicable</div></div> <div>Field Annotation: @HIDDEN</div>

268	donating_samples_saliva	Donating samples-Saliva	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table> Field Annotation: @HIDDEN	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										
269	donating_samples_csf	Donating samples-CSF	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table> Field Annotation: @HIDDEN	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										
270	left_over_material	Left over diagnostic material use	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table> Field Annotation: @HIDDEN	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										
271	donating_other_samples	Donating other samples	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table> Field Annotation: @HIDDEN	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										
272	protocols_allows_for_recru	Protocols allows for recruitment of anonymized patients (These are patient have been de-identified permanently)	dropdown (autocomplete) <table><tr><td>1</td><td>YES</td></tr><tr><td>2</td><td>NO</td></tr></table> Field Annotation: @HIDDEN	1	YES	2	NO				
1	YES										
2	NO										
273	permission_incidental_finding	1- Do you give your permission to be informed about incidental clinical findings following discussion by a "molecular board" that may decide that confirmation testing is required?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @HIDDEN	1	Yes	0	No				
1	Yes										
0	No										
274	subject_initials_incidental_finding	Subject Initials:	text Field Annotation: @HIDDEN								
275	permission_future_study	2- Do you give your permission for the investigator or staff to contact you regarding your willingness to participate in future research studies?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @HIDDEN	1	Yes	0	No				
1	Yes										
0	No										
276	subject_initials_future_study	Subject Initials:	text Field Annotation: @HIDDEN								
277	i_allow_the_research_team	3- I allow the Research Team to collect the following specimens:	radio <table><tr><td>1</td><td>Leftover samples only</td></tr><tr><td>2</td><td>Leftover and additional research samples, as specified above</td></tr></table> Field Annotation: @HIDDEN	1	Leftover samples only	2	Leftover and additional research samples, as specified above				
1	Leftover samples only										
2	Leftover and additional research samples, as specified above										
278	informed_about_incidental	Section Header: Informed about incidental clinical findings	dropdown (autocomplete) <table><tr><td>1</td><td>On</td></tr><tr><td>2</td><td>Off</td></tr><tr><td>3</td><td>Option</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	On	2	Off	3	Option	4	Not Applicable
1	On										
2	Off										
3	Option										
4	Not Applicable										

279	contact_you_for_future_res	Contact you for future research studies	dropdown (autocomplete) <table border="1"> <tr><td>1</td><td>On</td></tr> <tr><td>2</td><td>Off</td></tr> <tr><td>3</td><td>Option</td></tr> <tr><td>4</td><td>Not Applicable</td></tr> </table>	1	On	2	Off	3	Option	4	Not Applicable				
1	On														
2	Off														
3	Option														
4	Not Applicable														
280	leftover_samples_only	Leftover samples only	dropdown (autocomplete) <table border="1"> <tr><td>1</td><td>On</td></tr> <tr><td>2</td><td>Off</td></tr> <tr><td>3</td><td>Option</td></tr> <tr><td>4</td><td>Not Applicable</td></tr> </table>	1	On	2	Off	3	Option	4	Not Applicable				
1	On														
2	Off														
3	Option														
4	Not Applicable														
281	leftover_and_additional_re	Leftover and additional research samples	dropdown (autocomplete) <table border="1"> <tr><td>1</td><td>On</td></tr> <tr><td>2</td><td>Off</td></tr> <tr><td>3</td><td>Option</td></tr> <tr><td>4</td><td>Not Applicable</td></tr> </table>	1	On	2	Off	3	Option	4	Not Applicable				
1	On														
2	Off														
3	Option														
4	Not Applicable														
282	consent_form_metadata_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete						
0	Incomplete														
1	Unverified														
2	Complete														
Instrument: <b>Data Collection Form I - standard fields</b> (data_collection_form_i_standard_fields) <a href="#">^ Collapse</a>															
283	standard_fields	The study needs data from the following categories:(MRN, is included under PII, if you need to contact the patient address, phone and email might be needed) If the field not listed please go to Form II	checkbox <table border="1"> <tr><td>2</td><td>standard_fields__2</td><td>Personal Identifiable Information (PII)</td></tr> <tr><td>3</td><td>standard_fields__3</td><td>Frequently Used Fields (personal health data)</td></tr> <tr><td>4</td><td>standard_fields__4</td><td>PRIME - Recommended fields</td></tr> </table>	2	standard_fields__2	Personal Identifiable Information (PII)	3	standard_fields__3	Frequently Used Fields (personal health data)	4	standard_fields__4	PRIME - Recommended fields			
2	standard_fields__2	Personal Identifiable Information (PII)													
3	standard_fields__3	Frequently Used Fields (personal health data)													
4	standard_fields__4	PRIME - Recommended fields													
284	dcf_patient_study_number	Patient Study Number	radio <table border="1"> <tr><td>1</td><td>Unique Patient Study number</td></tr> </table> Field Annotation: @DEFAULT='1'	1	Unique Patient Study number										
1	Unique Patient Study number														
285	dcf_personal_identifiable Show the field ONLY if: [standard_fields(2)] = '1' or [standard_fields(4)] = '1'	Personal Identifiable Fields See below info from Policy: ACCESS TO SIDRA RECORDS FOR RESEARCH OR QUALITY IMPROVEMENT (QI) ACTIVITIES OR PUBLICATIONS	descriptive												
286	pii_names Show the field ONLY if: [standard_fields(2)] = '1'	3.1 Names	checkbox <table border="1"> <tr><td>1</td><td>pii_names__1</td><td>Participant name</td></tr> <tr><td>2</td><td>pii_names__2</td><td>Mother's name</td></tr> <tr><td>3</td><td>pii_names__3</td><td>Father's name</td></tr> <tr><td>4</td><td>pii_names__4</td><td>Sibling name(s)</td></tr> </table>	1	pii_names__1	Participant name	2	pii_names__2	Mother's name	3	pii_names__3	Father's name	4	pii_names__4	Sibling name(s)
1	pii_names__1	Participant name													
2	pii_names__2	Mother's name													
3	pii_names__3	Father's name													
4	pii_names__4	Sibling name(s)													
287	pii_names_details Show the field ONLY if: [pii_names(1)] = '1' and [pii_names(2)] = '1' and [pii_names(3)] = '1' and [pii_names(4)] = '1'	3.1. More details about names if needed	text												
288	pii_address Show the field ONLY if: [standard_fields(2)] = '1'	3.2 Housing location	radio <table border="1"> <tr><td>1</td><td>Address Details</td></tr> </table>	1	Address Details										
1	Address Details														
289	pii_address_details Show the field ONLY if: [pii_address] = '1'	3.2. More details about the address	text												
290	pii_sponsor Show the field ONLY if: [standard_fields(2)] = '1'	3.3. Employer/Sponsor	checkbox <table border="1"> <tr><td>1</td><td>pii_sponsor__1</td><td>Employer/Sponsor</td></tr> </table>	1	pii_sponsor__1	Employer/Sponsor									
1	pii_sponsor__1	Employer/Sponsor													
291	pii_sponsor_detail Show the field ONLY if: [pii_sponsor(1)] = '1'	3.3. More detail if needed	text												

292	pii_dates  Show the field ONLY if: [standard_fields(2)] = '1' or [standard_fields(4)] = '1'	3.4. All elements of dates (except year) for dates directly related to the Patient, including birth date, admission date, discharge date and date of death	checkbox <table><tr><td>1</td><td>pii_dates__1</td><td>Birth Date (PRIME recommended)</td></tr><tr><td>2</td><td>pii_dates__2</td><td>Admission Date (PRIME recommended)</td></tr><tr><td>3</td><td>pii_dates__3</td><td>Discharge Date</td></tr><tr><td>4</td><td>pii_dates__4</td><td>Date of Death</td></tr><tr><td>5</td><td>pii_dates__5</td><td>Date of Appointment (PRIME recommended)</td></tr></table>	1	pii_dates__1	Birth Date (PRIME recommended)	2	pii_dates__2	Admission Date (PRIME recommended)	3	pii_dates__3	Discharge Date	4	pii_dates__4	Date of Death	5	pii_dates__5	Date of Appointment (PRIME recommended)
1	pii_dates__1	Birth Date (PRIME recommended)																
2	pii_dates__2	Admission Date (PRIME recommended)																
3	pii_dates__3	Discharge Date																
4	pii_dates__4	Date of Death																
5	pii_dates__5	Date of Appointment (PRIME recommended)																
293	pii_dates_detail  Show the field ONLY if: [pii_dates(1)] = '1' or [pii_dates(2)] = '1' or [pii_dates(3)] = '1' or [pii_dates(4)] = '1' or [pii_dates(5)] = '1'	3.4. Elements of Dates, please provide more detail	text															
294	pii_phone  Show the field ONLY if: [standard_fields(2)] = '1'	3.5. Phone Number	checkbox <table><tr><td>1</td><td>pii_phone__1</td><td>Mobile number</td></tr><tr><td>2</td><td>pii_phone__2</td><td>Landline number</td></tr><tr><td>3</td><td>pii_phone__3</td><td>Alternative phone numbers</td></tr></table>	1	pii_phone__1	Mobile number	2	pii_phone__2	Landline number	3	pii_phone__3	Alternative phone numbers						
1	pii_phone__1	Mobile number																
2	pii_phone__2	Landline number																
3	pii_phone__3	Alternative phone numbers																
295	pii_phone_detail  Show the field ONLY if: [pii_phone(1)] = '1' or [pii_phone(2)] = '1' or [pii_phone(3)] = '1'	3.5. Phone number more details	text															
296	pii_email  Show the field ONLY if: [standard_fields(2)] = '1'	3.6. Electronic Mail Address	radio <table><tr><td>1</td><td>E-mail address</td></tr></table>	1	E-mail address													
1	E-mail address																	
297	pii_qid  Show the field ONLY if: [standard_fields(2)] = '1'	3.7. Qatar ID number	radio <table><tr><td>1</td><td>Qatar ID number</td></tr></table>	1	Qatar ID number													
1	Qatar ID number																	
298	pii_passport  Show the field ONLY if: [standard_fields(2)] = '1'	3.8. Passport Number	radio <table><tr><td>1</td><td>Passport Number</td></tr></table>	1	Passport Number													
1	Passport Number																	
299	pii_mrn  Show the field ONLY if: [standard_fields(2)] = '1' or [standard_fields(4)] = '1'	3.9. Medical Record Number (MRN)	radio <table><tr><td>1</td><td>MRN</td></tr></table>	1	MRN													
1	MRN																	
300	pii_mrn_detail  Show the field ONLY if: [pii_mrn] = '1'	3.9. MRN more details if needed	text															
301	pii_insurance_number  Show the field ONLY if: [standard_fields(2)] = '1'	3.10. Health or Insurance Plan Beneficiary Number	radio <table><tr><td>1</td><td>Health or Insurance Plan Beneficiary Number</td></tr></table>	1	Health or Insurance Plan Beneficiary Number													
1	Health or Insurance Plan Beneficiary Number																	
302	pii_insurance_number_detail  Show the field ONLY if: [pii_insurance_number] = '1'	3.10 Health and insurance number, please give more detail, like HAMAD Card number	text															
303	pii_bank_account  Show the field ONLY if: [standard_fields(2)] = '1'	3.11. Account Number	radio <table><tr><td>1</td><td>Bank Account number</td></tr></table>	1	Bank Account number													
1	Bank Account number																	
304	pii_car_number_plate  Show the field ONLY if: [standard_fields(2)] = '1'	3.12. Vehicle identifiers including license plate number	radio <table><tr><td>1</td><td>Car number plate</td></tr></table>	1	Car number plate													
1	Car number plate																	
305	pii_ip  Show the field ONLY if: [standard_fields(2)] = '1'	3.13. Internet Protocol (IP) address numbers	radio <table><tr><td>1</td><td>Personal identifiable IP address</td></tr></table>	1	Personal identifiable IP address													
1	Personal identifiable IP address																	
306	pii_url  Show the field ONLY if: [standard_fields(2)] = '1'	3.14. Web Universal Resource Locators (URLs)	radio <table><tr><td>1</td><td>Personal URL's</td></tr></table>	1	Personal URL's													
1	Personal URL's																	
307	pii_biometric  Show the field ONLY if: [standard_fields(2)] = '1'	3.15. Biometric identifiers including finger and voice prints	radio <table><tr><td>1</td><td>Biometric identifier</td></tr></table>	1	Biometric identifier													
1	Biometric identifier																	

308	pii_photo Show the field ONLY if: [standard_fields(2)] = '1'	3.16. Full face photographic images	radio <table><tr><td>1</td><td>Picture of Face</td></tr></table>	1	Picture of Face																			
1	Picture of Face																							
309	pii_other Show the field ONLY if: [standard_fields(2)] = '1'	3.17. Any other unique identifying number, characteristic or code	radio <table><tr><td>1</td><td>Other PII</td></tr></table>	1	Other PII																			
1	Other PII																							
310	pii_other_detail Show the field ONLY if: [pii_other] = '1'	3.17 more details	text																					
311	pii_comment_general Show the field ONLY if: [standard_fields(2)] = '1'	PII comment	text																					
312	dcf_medication Show the field ONLY if: [standard_fields(3)] = '1' or [standard_fields(4)] = '1'	Section Header: Medication (PRIME recommended)	checkbox <table><tr><td>1</td><td>dcf_medication__1</td><td>Commercial name of medication</td></tr><tr><td>2</td><td>dcf_medication__2</td><td>Active substance</td></tr><tr><td>3</td><td>dcf_medication__3</td><td>Prescribed Dosage (with unit)</td></tr><tr><td>4</td><td>dcf_medication__4</td><td>Frequency of application</td></tr><tr><td>5</td><td>dcf_medication__5</td><td>Prescription start date</td></tr><tr><td>6</td><td>dcf_medication__6</td><td>Duration of prescription</td></tr><tr><td>7</td><td>dcf_medication__7</td><td>Other</td></tr></table>	1	dcf_medication__1	Commercial name of medication	2	dcf_medication__2	Active substance	3	dcf_medication__3	Prescribed Dosage (with unit)	4	dcf_medication__4	Frequency of application	5	dcf_medication__5	Prescription start date	6	dcf_medication__6	Duration of prescription	7	dcf_medication__7	Other
1	dcf_medication__1	Commercial name of medication																						
2	dcf_medication__2	Active substance																						
3	dcf_medication__3	Prescribed Dosage (with unit)																						
4	dcf_medication__4	Frequency of application																						
5	dcf_medication__5	Prescription start date																						
6	dcf_medication__6	Duration of prescription																						
7	dcf_medication__7	Other																						
313	dcf_medication_details Show the field ONLY if: [dcf_medication(7)] = '1'	Provide details for Other Medication	text																					
314	dcf_diagnosis Show the field ONLY if: [standard_fields(3)] = '1' or [standard_fields(4)] = '1'	Diagnosis (PRIME recommended)	checkbox <table><tr><td>1</td><td>dcf_diagnosis__1</td><td>Diagnosis</td></tr><tr><td>2</td><td>dcf_diagnosis__2</td><td>ICD10 or ICD09 code</td></tr><tr><td>3</td><td>dcf_diagnosis__3</td><td>First time diagnosis identified (Date)</td></tr><tr><td>4</td><td>dcf_diagnosis__4</td><td>Human Phenotype Ontology (HPO code)</td></tr><tr><td>10</td><td>dcf_diagnosis__10</td><td>Other</td></tr></table>	1	dcf_diagnosis__1	Diagnosis	2	dcf_diagnosis__2	ICD10 or ICD09 code	3	dcf_diagnosis__3	First time diagnosis identified (Date)	4	dcf_diagnosis__4	Human Phenotype Ontology (HPO code)	10	dcf_diagnosis__10	Other						
1	dcf_diagnosis__1	Diagnosis																						
2	dcf_diagnosis__2	ICD10 or ICD09 code																						
3	dcf_diagnosis__3	First time diagnosis identified (Date)																						
4	dcf_diagnosis__4	Human Phenotype Ontology (HPO code)																						
10	dcf_diagnosis__10	Other																						
315	dcf_diagnosis_details Show the field ONLY if: [dcf_diagnosis(10)] = '1'	Provide details or additional information for Diagnosis Other	text																					
316	dcf_demographics Show the field ONLY if: [standard_fields(3)] = '1' or [standard_fields(4)] = '1'	Demographics	checkbox <table><tr><td>1</td><td>dcf_demographics__1</td><td>Nationality</td></tr><tr><td>2</td><td>dcf_demographics__2</td><td>Ethnicity (PRIME recommended)</td></tr><tr><td>3</td><td>dcf_demographics__3</td><td>Gender (PRIME recommended)</td></tr></table>	1	dcf_demographics__1	Nationality	2	dcf_demographics__2	Ethnicity (PRIME recommended)	3	dcf_demographics__3	Gender (PRIME recommended)												
1	dcf_demographics__1	Nationality																						
2	dcf_demographics__2	Ethnicity (PRIME recommended)																						
3	dcf_demographics__3	Gender (PRIME recommended)																						
317	dcf_standard_health Show the field ONLY if: [standard_fields(3)] = '1'	Standard Heath data (including vital signs)	checkbox <table><tr><td>1</td><td>dcf_standard_health__1</td><td>Age</td></tr><tr><td>2</td><td>dcf_standard_health__2</td><td>Weight</td></tr><tr><td>3</td><td>dcf_standard_health__3</td><td>Height</td></tr><tr><td>4</td><td>dcf_standard_health__4</td><td>Blood Pressure</td></tr><tr><td>5</td><td>dcf_standard_health__5</td><td>Heart Frequency</td></tr></table>	1	dcf_standard_health__1	Age	2	dcf_standard_health__2	Weight	3	dcf_standard_health__3	Height	4	dcf_standard_health__4	Blood Pressure	5	dcf_standard_health__5	Heart Frequency						
1	dcf_standard_health__1	Age																						
2	dcf_standard_health__2	Weight																						
3	dcf_standard_health__3	Height																						
4	dcf_standard_health__4	Blood Pressure																						
5	dcf_standard_health__5	Heart Frequency																						
318	data_collection_form_i_standard_fields_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete															
0	Incomplete																							
1	Unverified																							
2	Complete																							
Instrument: <b>Data Collection Form II - custom fields</b> (data_collection_form_ii_custom_fields) <a href="#">^ Collapse</a>																								
319	dcf_field_name_custom	Data Collection field name	text																					



320	dcf_type_of_field	Please select nature of field	<table><tr><td colspan="2">radio</td></tr><tr><td>1</td><td>Free text field</td></tr><tr><td>2</td><td>Yes / No answer</td></tr><tr><td>3</td><td>Drop-down list (single choice)</td></tr><tr><td>4</td><td>List to chose from (multiple choices possible)</td></tr><tr><td>5</td><td>Calculated field</td></tr><tr><td>6</td><td>Uploading something</td></tr></table>	radio		1	Free text field	2	Yes / No answer	3	Drop-down list (single choice)	4	List to chose from (multiple choices possible)	5	Calculated field	6	Uploading something
radio																	
1	Free text field																
2	Yes / No answer																
3	Drop-down list (single choice)																
4	List to chose from (multiple choices possible)																
5	Calculated field																
6	Uploading something																
321	dcf_description_field_cust	Description of collected field	notes														
322	dcf_special_custom	Specialties of the field(i.e. collection only once or at each visit, from participant only or also from sibling and parents etc...)	text														
323	dcf_comment_custom	Comment	text														
324	data_collection_form_ii_custom_fields_complete	Section Header: <i>Form Status</i> Complete?	<table><tr><td colspan="2">dropdown</td></tr><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	dropdown		0	Incomplete	1	Unverified	2	Complete						
dropdown																	
0	Incomplete																
1	Unverified																
2	Complete																

Instrument: **Documents related to your IRB** (documents\_related\_to\_your\_irb)[^ Collapse](#)

325	infor_regulatory_binder	Documents. All non-patient related Documents can be uploaded.	descriptive														
326	binder_chapter	Select Chapter	<div>radio</div> <table><tr><td>1</td><td>I STUDY CONCEPT (1)</td></tr><tr><td>2</td><td>II STUDY PLANNING &amp; CREATION (2)</td></tr><tr><td>3</td><td>III STUDY ACTIVATION AND CONDUCT (3)</td></tr><tr><td>4</td><td>IV STUDY CLOSURE &amp; ANALYSIS (4)</td></tr></table>	1	I STUDY CONCEPT (1)	2	II STUDY PLANNING & CREATION (2)	3	III STUDY ACTIVATION AND CONDUCT (3)	4	IV STUDY CLOSURE & ANALYSIS (4)						
1	I STUDY CONCEPT (1)																
2	II STUDY PLANNING & CREATION (2)																
3	III STUDY ACTIVATION AND CONDUCT (3)																
4	IV STUDY CLOSURE & ANALYSIS (4)																
327	<div>select_study_concept</div> <div>Show the field ONLY if: [binder_chapter] = '1'</div>	Study Concept	<div>radio</div> <table><tr><td>1</td><td>Budget or Funding source and approval documentation (1.1)</td></tr><tr><td>2</td><td>PI and study team contact information (1.2)</td></tr><tr><td>3</td><td>Any relevant information or communication at early stage, if applicable (1.3)</td></tr><tr><td>4</td><td>Agreements and contracts (e.g., MTA, NDA, RCA) (1.4)</td></tr><tr><td>5</td><td>Other participating site if multi-center research and Sidra is the sponsor (1.5)</td></tr><tr><td>6</td><td>Other study documents (e.g., foreign collaborators assurance, etc.) (1.6)</td></tr></table>	1	Budget or Funding source and approval documentation (1.1)	2	PI and study team contact information (1.2)	3	Any relevant information or communication at early stage, if applicable (1.3)	4	Agreements and contracts (e.g., MTA, NDA, RCA) (1.4)	5	Other participating site if multi-center research and Sidra is the sponsor (1.5)	6	Other study documents (e.g., foreign collaborators assurance, etc.) (1.6)		
1	Budget or Funding source and approval documentation (1.1)																
2	PI and study team contact information (1.2)																
3	Any relevant information or communication at early stage, if applicable (1.3)																
4	Agreements and contracts (e.g., MTA, NDA, RCA) (1.4)																
5	Other participating site if multi-center research and Sidra is the sponsor (1.5)																
6	Other study documents (e.g., foreign collaborators assurance, etc.) (1.6)																
328	<div>select_planning_creation</div> <div>Show the field ONLY if: [binder_chapter] = '2'</div>	STUDY PLANNING & CREATION	<div>radio</div> <table><tr><td>1</td><td>IIA Institutional Review Board (IRB) Approvals and correspondence (2.1)</td></tr><tr><td>2</td><td>IIB Approved and Signed Protocol and Amendments (2.2)</td></tr><tr><td>3</td><td>IIC Informed Consent Documents (2.3)</td></tr><tr><td>7</td><td>IIC Verbal Assent Script</td></tr><tr><td>4</td><td>IID Other Approvals and Correspondence (2.4)</td></tr><tr><td>5</td><td>IIE Investigator Qualifications and Trainings Documentation (2.5)</td></tr><tr><td>6</td><td>IIF Data Collection Sheet</td></tr></table>	1	IIA Institutional Review Board (IRB) Approvals and correspondence (2.1)	2	IIB Approved and Signed Protocol and Amendments (2.2)	3	IIC Informed Consent Documents (2.3)	7	IIC Verbal Assent Script	4	IID Other Approvals and Correspondence (2.4)	5	IIE Investigator Qualifications and Trainings Documentation (2.5)	6	IIF Data Collection Sheet
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5	IIE Investigator Qualifications and Trainings Documentation (2.5)																
6	IIF Data Collection Sheet																
329	<div>select_iaa</div> <div>Show the field ONLY if: [select_planning_creation] = '1'</div>	IIA Institutional Review Board (IRB) Approvals and correspondence (2.1)	<div>radio</div> <table><tr><td>1</td><td>IRB approval letters (**1) (2.1.1)</td></tr><tr><td>2</td><td>IRB-406 Initial Review Form (IRB application) (incl draft) (2.1.2)</td></tr><tr><td>3</td><td>IRB-407 Continuing Review Application (incl draft) (2.1.3)</td></tr><tr><td>4</td><td>IRB-408 Modification Application Form (2.1.4)</td></tr><tr><td>5</td><td>IRB correspondence (2.1.5)</td></tr></table>	1	IRB approval letters (**1) (2.1.1)	2	IRB-406 Initial Review Form (IRB application) (incl draft) (2.1.2)	3	IRB-407 Continuing Review Application (incl draft) (2.1.3)	4	IRB-408 Modification Application Form (2.1.4)	5	IRB correspondence (2.1.5)				
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4	IRB-408 Modification Application Form (2.1.4)																
5	IRB correspondence (2.1.5)																

330	<div>select_iib</div> <div>Show the field ONLY if: [select_planning_creation] = '2'</div>	IIB Approved and Signed Protocol and Amendments (2.2)	<div>radio</div> <div><div>1</div>IRB-approved protocol, with signed principal investigator (PI) (2.2.1)</div> <div><div>2</div>IRB-approved blank Case Report Forms (2.2.2)</div> <div><div>3</div>IRB-approved protocol amendments (2.2.3)</div> <div><div>4</div>Study materials (e.g., questionnaires, flyers...), (2.2.4)</div> <div><div>5</div>(do not use, for future additions)</div>
331	<div>select_iic</div> <div>Show the field ONLY if: [select_planning_creation] = '3'</div>	IIC Informed Consent Documents (2.3) (only template upload, no documents filled with any information by patients!)	<div>radio</div> <div><div>1</div>IRB-400/401 (English/Arabic) Informed Consent Form (2.3.1)</div> <div><div>2</div>IRB-402/403 (English/Arabic) Parental Permission Form (2.3.2)</div> <div><div>3</div>IRB 404/405 (English/Arabic) Assent Form (Child) (2.3.3)</div>
332	<div>select_iid</div> <div>Show the field ONLY if: [select_planning_creation] = '4'</div>	IID Other Approvals and Correspondence (2.4)	<div>radio</div> <div><div>1</div>Other Approvals, if applicable (e.g., IBC, IACUC, RRC, etc.) (**2) (2.4.1)</div> <div><div>2</div>Other Correspondence (e.g., clarification requested, amendment etc.), (2.4.2)</div>
333	<div>select_iie</div> <div>Show the field ONLY if: [select_planning_creation] = '5'</div>	IIE Investigator Qualifications and Trainings Documentation (2.5)	<div>radio</div> <div><div>1</div>"Updated CV from all Site personnel involved (listed on IRB-409)" (**3) (2.5.1)</div> <div><div>2</div>L-500-(A) Research Related Declarations of Interest (**4) (2.5.2)</div> <div><div>3</div>Documentation of CITI Training (**5) (2.5.3)</div> <div><div>4</div>Other trainings (e.g., Biosafety, etc.) (**6) (2.5.4)</div>
334	<div>select_activation</div> <div>Show the field ONLY if: [binder_chapter] = '3'</div>	STUDY ACTIVATION AND CONDUCT (3)	<div>radio</div> <div><div>1</div>IIIA Study Communication (3.1)</div> <div><div>2</div>IIIB Delegation of Responsibilities Log (All versions) (3.2)</div> <div><div>3</div>IIIC Subject Screening/Enrollment Log (All versions) (3.3)</div> <div><div>4</div>IIID Subject Informed Consent Documents (may be kept in a separate binder) (3.4)</div> <div><div>5</div>IIIE Data Management (may be kept in a separate binder) (3.5)</div> <div><div>6</div>IIIF Human Samples Management (3.6)</div> <div><div>7</div>IIIG Safety Documents (3.7)</div>
335	<div>select_iiia</div> <div>Show the field ONLY if: [select_activation] = '1'</div>	IIIA Study Communication (3.1)	<div>radio</div> <div><div>1</div>Interim/Progress report (**7) (3.1.1)</div> <div><div>2</div>Relevant communication (e.g., reporting to funding body, CRO approval if applicable) (3.1.2)</div> <div><div>3</div>Notes to File, (3.1.4)</div>
336	<div>select_iiib</div> <div>Show the field ONLY if: [select_activation] = '2'</div>	IIIB Delegation of Responsibilities Log (All versions) (3.2)	<div>radio</div> <div><div>1</div>Delegation of Responsibilities Log (3.2.1)</div> <div><div>2</div>IRB-409 Personnel Form (3.2.2)</div>
337	<div>select_iiic</div> <div>Show the field ONLY if: [select_activation] = '3'</div>	IIIC Subject Screening/Enrollment Log (All versions) (3.3)	<div>radio</div> <div><div>1</div>Subject Screening/ Enrollment Log (make sure no patient data on it) (3.3.1)</div> <div><div>2</div>Subject Identification Log (Linking Log) (**8) (3.3.2)</div>
338	<div>select_iiid</div> <div>Show the field ONLY if: [select_activation] = '4'</div>	IIID Subject Informed Consent Documents (may be kept in a separate binder) (3.4)	<div>radio</div> <div><div>1</div>Subject Informed Consent Log (**8) (3.4.1)</div> <div><div>2</div>Signed Subject Informed Consent (**8) (3.4.2)</div>
339	<div>select_iiie</div> <div>Show the field ONLY if: [select_activation] = '5'</div>	IIIE Data Management (may be kept in a separate binder) (3.5)	<div>radio</div> <div><div>1</div>Note to file (e.g., refer to where data are kept/stored) (3.5.1)</div> <div><div>2</div>R004 Research Data Access Form</div>

340	<div>select_iiif</div> <div>Show the field ONLY if: [select_activation] = '6'</div>	IIIF Human Samples Management (3.6)	<div>radio</div> <div><div>1</div><div>Research Request Form (3.6.1)</div></div> <div><div>2</div><div>Sample Log (3.6.2)</div></div>
341	<div>select_iiig</div> <div>Show the field ONLY if: [select_activation] = '7'</div>	IIIG Safety Documents (3.7)	<div>radio</div> <div><div>1</div><div>SAE/AE Reporting Form (3.7.1)</div></div> <div><div>2</div><div>Deviations/Violations tracking (3.7.2)</div></div> <div><div>3</div><div>"Corrective and preventive actions decision taken by the IRB for non-conformities findings." (3.7.8)</div></div>
342	<div>select_closure</div> <div>Show the field ONLY if: [binder_chapter] = '4'</div>	STUDY CLOSURE & ANALYSIS (4)	<div>radio</div> <div><div>1</div><div>Final Report to IRB and IRB closure acknowledgment (4.1)</div></div> <div><div>2</div><div>Final Report to funding body (**9) (4.2)</div></div> <div><div>3</div><div>Financial Close-out (if funding body involved) (4.3)</div></div> <div><div>4</div><div>Publications (**10) (4.4)</div></div> <div><div>5</div><div>Results (**10) (4.5)</div></div>
343	<div>what_exist_already</div> <div>Show the field ONLY if: [select_iiic] = '1' or [select_iiic] = '2' or [select_iiid] = '1'</div>	(**8) Patient related data not to be uploaded to PMO RedCap	descriptive
344	<div>binder_doc_title</div>	Add a document title	text
345	<div>stamped_or_draft</div>	Please select	<div>radio</div> <div><div>1</div><div>Stamped (by IRB office)</div></div> <div><div>2</div><div>Draft</div></div> <div><div>5</div><div>Version submitted to IRB</div></div> <div><div>4</div><div>Signed Version</div></div> <div><div>3</div><div>For Information</div></div>
346	<div>pack_in_irbnet</div>	Select corresponding folder / package in IRBNet (if applicable)	<div>dropdown (autocomplete)</div> <div><div>1</div><div>Designer</div></div> <div><div>2</div><div>Pk 01</div></div> <div><div>3</div><div>Pk 02</div></div> <div><div>4</div><div>Pk 03</div></div> <div><div>5</div><div>Pk 04</div></div> <div><div>6</div><div>Pk 05</div></div> <div><div>7</div><div>Pk 06</div></div> <div><div>8</div><div>Pk 07</div></div> <div><div>9</div><div>Pk 08</div></div> <div><div>10</div><div>Pk 09</div></div> <div><div>11</div><div>Pk 10</div></div> <div><div>12</div><div>Pk 11</div></div> <div><div>13</div><div>Pk 12</div></div> <div><div>14</div><div>Pk 13</div></div> <div><div>15</div><div>Pk 14</div></div> <div><div>16</div><div>Pk 15</div></div> <div><div>17</div><div>Pk 16</div></div> <div><div>18</div><div>Pk 17</div></div> <div><div>19</div><div>Pk 18</div></div> <div><div>20</div><div>Pk 19</div></div> <div><div>21</div><div>Pk 20</div></div> <div><div>22</div><div>Pk 21</div></div> <div><div>23</div><div>Pk 22</div></div> <div><div>24</div><div>Pk 23</div></div> <div><div>25</div><div>Pk 24</div></div> <div><div>26</div><div>Pk 25</div></div>
347	<div>binder_doc_date</div>	Relevant date for the document	text (date_ymd)

348	upload_binder_doc	Upload the Document	file																														
	<p>Show the field ONLY if:</p> <p>[select_study_concept] = '1' or          [select_study_concept] = '2' or          [select_study_concept] = '3' or          [select_study_concept] = '4' or          [select_study_concept] = '5' or          [select_study_concept] = '5' or          [select_study_concept] = '6' or          [select_planning_creation] = '1' or [select_planning_creation] = '2' or [select_planning_creation] = '3' or [select_planning_creation] = '4' or [select_planning_creation] = '5' or [select_planning_creation] = '6' or [select_planning_creation] = '7' or          [select_iiia] = '1' or [select_iiia] = '2' or [select_iiia] = '3' or [select_iiia] = '4' or [select_iiia] = '5' or          [select_iib] = '1' or [select_iib] = '2' or [select_iib] = '3' or [select_iib] = '4' or [select_iic] = '1' or [select_iic] = '2' or [select_iic] = '3' or [select_iid] = '1' or [select_iid] = '2' or [select_iie] = '1' or [select_iie] = '2' or [select_iie] = '3' or [select_iie] = '4' or [select_iiia] = '1' or [select_iiia] = '2' or [select_iiia] = '3' or [select_iiib] = '1' or [select_iiib] = '2' or [select_iiie] = '1' or [select_iiif] = '1' or [select_iiif] = '2' or [select_iiig] = '1' or [select_iiig] = '2' or [select_iiig] = '3' or [select_closure] = '1' or [select_closure] = '2' or [select_closure] = '3' or [select_closure] = '4' or [select_closure] = '5' or [select_iiic] = '1' or [select_planning_creation] = '6' or [select_activation] = '5' or [assign_later] = '1'</p>																																
349	comment_binder_doc	Comment	text																														
350	assign_later	Upload assign later	radio 1 click																														
351	documents_related_to_your_irb_complete	Section Header: <i>Form Status</i> Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete																														
Instrument: <b>PHI - PRIME</b> (phi_prime) <a href="#">^ Collapse</a>																																	
352	phi_prime	Please click which PHI data are collected for your study:	checkbox <table border="1"> <tr> <td>1</td> <td>phi_prime__1</td> <td>Day of Birth (the month and year are already in PRIME)</td> </tr> <tr> <td>2</td> <td>phi_prime__2</td> <td>MRN</td> </tr> <tr> <td>3</td> <td>phi_prime__3</td> <td>HC</td> </tr> <tr> <td>4</td> <td>phi_prime__4</td> <td>QID</td> </tr> <tr> <td>5</td> <td>phi_prime__5</td> <td>Fist Name</td> </tr> <tr> <td>6</td> <td>phi_prime__6</td> <td>Middle names</td> </tr> <tr> <td>7</td> <td>phi_prime__7</td> <td>Last Name</td> </tr> <tr> <td>8</td> <td>phi_prime__8</td> <td>Home address</td> </tr> <tr> <td>9</td> <td>phi_prime__9</td> <td>Phone mobile</td> </tr> <tr> <td>10</td> <td>phi_prime__10</td> <td>Phone home</td> </tr> </table>	1	phi_prime__1	Day of Birth (the month and year are already in PRIME)	2	phi_prime__2	MRN	3	phi_prime__3	HC	4	phi_prime__4	QID	5	phi_prime__5	Fist Name	6	phi_prime__6	Middle names	7	phi_prime__7	Last Name	8	phi_prime__8	Home address	9	phi_prime__9	Phone mobile	10	phi_prime__10	Phone home
1	phi_prime__1	Day of Birth (the month and year are already in PRIME)																															
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8	phi_prime__8	Home address																															
9	phi_prime__9	Phone mobile																															
10	phi_prime__10	Phone home																															
353	data_collection_form1	Upload related approved data collection form	file																														

354	pmo_vetting_phi_prime Show the field ONLY if: [pmo_vetting_phi_on_prime] = '1'	Data vetted by PMO, all correct	radio 1 Yes 2 No
355	phi_prime_complete	Section Header: <i>Form Status</i> Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: <b>Prime Access Request Form</b> (prime_access_request_form) <a href="#">^ Collapse</a>			
356	access_request_date_prime	Date of Request	text (date_dmy)
357	info_submit_prime_1	Once you have selected in the instrument "People on IRB" the role of each person with access to prime. (see image below) - you can submit your request here.  If you would like to submit a change request, you can chose the option below and pleas enter the new request.	descriptive
358	submit_prime	Section Header: <i>Submission</i> Submit Access to Prime, as per selection for each person in the instrument "People on IRB".	radio 1 Submit
359	change_access_prime	Section Header: A change to an existing request is needed. (including removal of access)	radio 1 Yes 2 No
360	explain_change Show the field ONLY if: [change_access_prime] = '1'	Please let us know what needs to be changed	notes
361	submit_change_prime_access Show the field ONLY if: [change_access_prime] = '1'	Submit Change Request	radio 1 Submit
362	doc_access_prime Show the field ONLY if: [change_access_prime] = '1'	Upload supporting document if necessary	file
363	status_pmo_approval1 Show the field ONLY if: [add_prime_approval] = '1'	Section Header: <i>PMO use only below</i> StatusPMO has checked all entries and has ...	radio 1 Approved 2 Open Questions
364	prime_access_request_form_c omplete	Section Header: <i>Form Status</i> Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: <b>PMO Internal</b> (pmo_internal) <a href="#">^ Collapse</a>			
365	irbnet_access	Access to IRB Net:	checkbox 1 irbnet_access__1 Christian 2 irbnet_access__2 Lara 3 irbnet_access__3 Wadha 4 irbnet_access__4 PMO 10 irbnet_access__10 Not registered in IRBNet
366	add_prime_approval	Section Header: Add PRIME Approval for People on IRB	radio 1 Yes 2 No
367	pmo_vetting_phi_on_prime	Add Prime Approval on PHI data for Prime	radio 1 Yes 2 No
368	target1	Target disease[location_sidra_outpatient] [location_regular_patient]	text

369	tors_summary	IRBNet info: [tors_treatment_research], [tors_prevention_research], [tors_diagnostic_research], [tors_screening_research], [tors_quality_of_life_research], [tors_genetic_study], [tors_precision_medicine], [tors_epidemiological_study], [tors_data_repository_for_futur], [tors_specimen_repository], [tors_comparative_research], [tors_supportive_care_research], [tors_chart_review_analys], [tors_analysis_of_existing_biol], [tors_other1], [tors_other2]	descriptive									
370	sample_type_irb	Sample type	text									
371	assoiatedprojects_yn	The IRB approval letter does mention all of the projects associated with it. In application form: [sdr_number]	radio <table border="1"> <tr><td>0</td><td>No</td></tr> <tr><td>1</td><td>Yes,</td></tr> <tr><td>2</td><td>Not Applicable</td></tr> </table>	0	No	1	Yes,	2	Not Applicable			
0	No											
1	Yes,											
2	Not Applicable											
372	txt_morethan1	More than 1 project associated	text Field Annotation: @HIDDEN									
373	exempt_irb_add_person	Evidence for adding people to exempt protocols, letter from IRB	descriptive									
374	comment_pmo1	Comment	text									
375	info_check_list	[intro] [background] [number_of_subjects_q] =if([intro]=1,1,0)+if([background]=1,1,0)+if([number_of_subjects_q]=1,1,0)	descriptive Field Annotation: @HIDDEN									
376	check_check_list	check list filled?	calc Calculation: if([intro]=1,1,0) Field Annotation: @HIDDEN									
377	pmo_internal_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete			
0	Incomplete											
1	Unverified											
2	Complete											
Instrument: <b>PMO Inspection Checklist</b> (pmo_inspection_checklist) <a href="#">^ Collapse</a>												
378	date_big_check	Date big check	text (date_dmy)									
379	logged_in_user	Logged person first open the inspection	text Field Annotation: @HIDDEN @USERNAME									
380	shareddrive1	Section Header: <i>Data on Shared Drive</i> Folder Created	checkbox <table border="1"> <tr><td>1</td><td>shareddrive1__1</td><td>Not Checked</td></tr> <tr><td>2</td><td>shareddrive1__2</td><td>Checked - OK</td></tr> <tr><td>3</td><td>shareddrive1__3</td><td>Checked - Attention Needed</td></tr> </table>	1	shareddrive1__1	Not Checked	2	shareddrive1__2	Checked - OK	3	shareddrive1__3	Checked - Attention Needed
1	shareddrive1__1	Not Checked										
2	shareddrive1__2	Checked - OK										
3	shareddrive1__3	Checked - Attention Needed										
381	shareddrive2	Folder with IRB created/exists	checkbox <table border="1"> <tr><td>1</td><td>shareddrive2__1</td><td>Not Checked</td></tr> <tr><td>2</td><td>shareddrive2__2</td><td>Checked - OK</td></tr> <tr><td>3</td><td>shareddrive2__3</td><td>Checked - Attention Needed</td></tr> </table>	1	shareddrive2__1	Not Checked	2	shareddrive2__2	Checked - OK	3	shareddrive2__3	Checked - Attention Needed
1	shareddrive2__1	Not Checked										
2	shareddrive2__2	Checked - OK										
3	shareddrive2__3	Checked - Attention Needed										
382	shareddrive3	Re-Created IRBNet folder structure Upload documents	checkbox <table border="1"> <tr><td>1</td><td>shareddrive3__1</td><td>Not Checked</td></tr> <tr><td>2</td><td>shareddrive3__2</td><td>Checked - OK</td></tr> <tr><td>3</td><td>shareddrive3__3</td><td>Checked - Attention Needed</td></tr> </table>	1	shareddrive3__1	Not Checked	2	shareddrive3__2	Checked - OK	3	shareddrive3__3	Checked - Attention Needed
1	shareddrive3__1	Not Checked										
2	shareddrive3__2	Checked - OK										
3	shareddrive3__3	Checked - Attention Needed										
383	attention_s_drive	What needs to be done?  Show the field ONLY if: [shareddrive2(3)] = '1' or [shareddrive3(3)] = '1' or [shareddrive1(3)] = '1'	notes									
384	people_cross_chk	Section Header: <i>IRB Application Check</i> Cross check info application and on people	radio (Matrix) <table border="1"> <tr><td>1</td><td>Not Checked (this time)</td></tr> <tr><td>2</td><td>Checked - OK</td></tr> <tr><td>3</td><td>Checked - Attention Needed</td></tr> </table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention Needed			
1	Not Checked (this time)											
2	Checked - OK											
3	Checked - Attention Needed											
385	lpi_responsibility	Tick all boxes for the LPI for responsibilities	radio (Matrix) <table border="1"> <tr><td>1</td><td>Not Checked (this time)</td></tr> <tr><td>2</td><td>Checked - OK</td></tr> <tr><td>3</td><td>Checked - Attention Needed</td></tr> </table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention Needed			
1	Not Checked (this time)											
2	Checked - OK											
3	Checked - Attention Needed											

386	I500_connect	Ensure L-500A is connected	radio (Matrix) <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention Needed</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention Needed
1	Not Checked (this time)								
2	Checked - OK								
3	Checked - Attention Needed								
387	number_patients	Check number of patients at Sidra and elsewhere	radio (Matrix) <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention Needed</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention Needed
1	Not Checked (this time)								
2	Checked - OK								
3	Checked - Attention Needed								
388	sdr_no_chk	SDR mentioned and correct	radio (Matrix) <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention Needed</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention Needed
1	Not Checked (this time)								
2	Checked - OK								
3	Checked - Attention Needed								
389	prime_approval	Add the PRIME approval	radio (Matrix) <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention Needed</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention Needed
1	Not Checked (this time)								
2	Checked - OK								
3	Checked - Attention Needed								
390	upload_application	Upload Application in first instrument	radio (Matrix) <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention Needed</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention Needed
1	Not Checked (this time)								
2	Checked - OK								
3	Checked - Attention Needed								
391	application_action  Show the field ONLY if: [people_cross_chk] = '3' or [lpi_responsibility] = '3' or [I500_connect] = '3' or [number_patients] = '3' or [sdr_no_chk] = '3' or [prime_approval] = '3' or [upload_application] = '3'	IRB Application needs Attention	notes						
392	expiry_dt	Section Header: <i>Check Approval Letter</i> Check correct expiry date	radio (Matrix) <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention needed</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention needed
1	Not Checked (this time)								
2	Checked - OK								
3	Checked - Attention needed								
393	type_chk	Check for type of approval (exempt, expedited, full)	radio (Matrix) <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention needed</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention needed
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2	Checked - OK								
3	Checked - Attention needed								
394	sample_size	Check approved Sample size	radio (Matrix) <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention needed</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention needed
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395	upload_approval	Upload Application in first instrument	radio (Matrix) <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention needed</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention needed
1	Not Checked (this time)								
2	Checked - OK								
3	Checked - Attention needed								
396	approval_action  Show the field ONLY if: [expiry_dt] = '3' or [type_chk] = '3' or [sample_size] = '3' or [upload_approval] = '3'	Approval Letter needs Attention	notes						
397	ppl_on_protocol	Section Header: <i>Protocol / Proposal Check</i> Check people on protocol reflected on application	radio (Matrix) <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention Needed</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention Needed
1	Not Checked (this time)								
2	Checked - OK								
3	Checked - Attention Needed								

398	sample_size_protocol	Check sample size (for number per year, including siblings or parents)	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention Needed</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention Needed		
1	Not Checked (this time)										
2	Checked - OK										
3	Checked - Attention Needed										
399	retro_chk	If retrospective check if that is true	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention Needed</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention Needed		
1	Not Checked (this time)										
2	Checked - OK										
3	Checked - Attention Needed										
400	upload_proposal	Upload Application in first instrument	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention Needed</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention Needed		
1	Not Checked (this time)										
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401	proposal_action  Show the field ONLY if: [ppl_on_protocol] = '3' or [sample_size_protocol] = '3' or [retro_chk] = '3' or [upload_proposal] = '3'	Proposal needs Attention	notes								
402	digitize_consent	Section Header: <i>Check 2 times a year</i> Consent Form Content digitized	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention Needed</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention Needed	4	Not Applicable
1	Not Checked (this time)										
2	Checked - OK										
3	Checked - Attention Needed										
4	Not Applicable										
403	consent_meta	Create consent Meta Data	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention Needed</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention Needed	4	Not Applicable
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3	Checked - Attention Needed										
4	Not Applicable										
404	cros_chk_phi	Cross check PHI Prime	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Not Checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention Needed</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	Not Checked (this time)	2	Checked - OK	3	Checked - Attention Needed	4	Not Applicable
1	Not Checked (this time)										
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3	Checked - Attention Needed										
4	Not Applicable										
405	consent_action_chk  Show the field ONLY if: [digitize_consent] = '3' or [consent_meta] = '3' or [cros_chk_phi] = '3'	Consent Form needs Attention	notes								
406	phi_cross_chk2	Section Header: <i>Data collection Form</i> Cross Check Instrument PHI Prime	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Not checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention Needed</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	Not checked (this time)	2	Checked - OK	3	Checked - Attention Needed	4	Not Applicable
1	Not checked (this time)										
2	Checked - OK										
3	Checked - Attention Needed										
4	Not Applicable										
407	consent_collect_cross	Cross Check Fields and Consent Form	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Not checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - Attention Needed</td></tr><tr><td>4</td><td>Not Applicable</td></tr></table>	1	Not checked (this time)	2	Checked - OK	3	Checked - Attention Needed	4	Not Applicable
1	Not checked (this time)										
2	Checked - OK										
3	Checked - Attention Needed										
4	Not Applicable										
408	datacoll_action  Show the field ONLY if: [phi_cross_chk2] = '3' or [consent_collect_cross] = '3'	Data collection approach needs some action	notes								
409	base_data1	Section Header: <i>IRBNet Data Import</i> Base data Report (imported, less than 3 months old)	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Not checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - needs Attention</td></tr></table>	1	Not checked (this time)	2	Checked - OK	3	Checked - needs Attention		
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3	Checked - needs Attention										



410	active_protocols	Active Protocols Report (imported, less than 3 months old)	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Not checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - needs Attention</td></tr></table>	1	Not checked (this time)	2	Checked - OK	3	Checked - needs Attention
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2	Checked - OK								
3	Checked - needs Attention								
411	irb_ppl_import	Peopel on IRB Report (imported, less than 3 months old)	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Not checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - needs Attention</td></tr></table>	1	Not checked (this time)	2	Checked - OK	3	Checked - needs Attention
1	Not checked (this time)								
2	Checked - OK								
3	Checked - needs Attention								
412	coolaboration_report	Collaboration Report (imported, less than 3 months old)	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Not checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - needs Attention</td></tr></table>	1	Not checked (this time)	2	Checked - OK	3	Checked - needs Attention
1	Not checked (this time)								
2	Checked - OK								
3	Checked - needs Attention								
413	collaboration_contract	Check if Collaboration has Contract already	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Not checked (this time)</td></tr><tr><td>2</td><td>Checked - OK</td></tr><tr><td>3</td><td>Checked - needs Attention</td></tr></table>	1	Not checked (this time)	2	Checked - OK	3	Checked - needs Attention
1	Not checked (this time)								
2	Checked - OK								
3	Checked - needs Attention								
414	attention_irbnet_import  Show the field ONLY if: [coolaboration_report] = '3' or [irb_ppl_import] = '3' or [active_protocols] = '3' or [base_data 1] = '3'	IRBNet Import Attention needed:	notes						
415	inspection_comment	Comment	notes						
416	pmo_inspection_checklist_complete	Section Header: <i>Form Status</i> Complete?	<div>dropdown</div> <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: <b>PMO Internal Documents</b> (pmo_internal_documents) <div>^ Collapse</div>									
417	internaldocs_pmo	Possibility to upload documents relevant for the project	descriptive						
418	title_internaldoc	Description of the document	text						
419	internaldoc_upload	Upload the document	file						
420	pmo_internal_documents_complete	Section Header: <i>Form Status</i> Complete?	<div>dropdown</div> <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
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2	Complete								
Instrument: <b>Cerner Registered Enrollment Forms</b> (cerner_registered_enrollment_forms) <div>^ Collapse</div>									

421	month_year	Month / Year	dropdown (autocomplete) <table><tr><td>1</td><td>Jan 2020</td></tr><tr><td>2</td><td>Feb 2020</td></tr><tr><td>3</td><td>Mar 2020</td></tr><tr><td>4</td><td>Apr 2020</td></tr><tr><td>5</td><td>May 2020</td></tr><tr><td>6</td><td>Jun 2020</td></tr><tr><td>7</td><td>Jul 2020</td></tr><tr><td>8</td><td>Aug 2020</td></tr><tr><td>9</td><td>Sep 2020</td></tr><tr><td>10</td><td>Oct 2020</td></tr><tr><td>11</td><td>Nov 2020</td></tr><tr><td>12</td><td>Dec 2020</td></tr><tr><td>13</td><td>Jan 2021</td></tr><tr><td>14</td><td>Feb 2021</td></tr><tr><td>15</td><td>Mar 2021</td></tr><tr><td>16</td><td>Apr 2021</td></tr><tr><td>17</td><td>May 2021</td></tr><tr><td>18</td><td>Jun 2021</td></tr><tr><td>19</td><td>Jul 2021</td></tr><tr><td>20</td><td>Aug 2021</td></tr><tr><td>21</td><td>Sep 2021</td></tr><tr><td>22</td><td>Oct 2021</td></tr><tr><td>23</td><td>Nov 2021</td></tr><tr><td>24</td><td>Dec 2021</td></tr><tr><td>25</td><td>Jan 2022</td></tr><tr><td>26</td><td>Feb 2022</td></tr><tr><td>27</td><td>Mar 2022</td></tr><tr><td>28</td><td>Apr 2022</td></tr><tr><td>29</td><td>May 2022</td></tr><tr><td>30</td><td>Jun 2022</td></tr><tr><td>31</td><td>Jul 2022</td></tr><tr><td>32</td><td>Aug 2022</td></tr><tr><td>33</td><td>Sep 2022</td></tr><tr><td>34</td><td>Oct 2022</td></tr><tr><td>35</td><td>Nov 2022</td></tr><tr><td>36</td><td>Dec 2022</td></tr></table>	1	Jan 2020	2	Feb 2020	3	Mar 2020	4	Apr 2020	5	May 2020	6	Jun 2020	7	Jul 2020	8	Aug 2020	9	Sep 2020	10	Oct 2020	11	Nov 2020	12	Dec 2020	13	Jan 2021	14	Feb 2021	15	Mar 2021	16	Apr 2021	17	May 2021	18	Jun 2021	19	Jul 2021	20	Aug 2021	21	Sep 2021	22	Oct 2021	23	Nov 2021	24	Dec 2021	25	Jan 2022	26	Feb 2022	27	Mar 2022	28	Apr 2022	29	May 2022	30	Jun 2022	31	Jul 2022	32	Aug 2022	33	Sep 2022	34	Oct 2022	35	Nov 2022	36	Dec 2022
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422	no_new_enrollment	Number of Enrollment Forms	text																																																																								
423	cerner_registered_enrollment_forms_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete																																																																		
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Instrument: <b>CTO Monitoring Documents</b> (cto_monitoring_documents) <div>^ Collapse</div>																																																																											
424	explain_cto	Here you can store the templates for CTO documents	descriptive																																																																								
425	monitoring_pro	PRO - O - Monitoring Activity for Clinical Trials	descriptive																																																																								
426	monitoring_plan	Appendix I - Monitoring Plan template	descriptive																																																																								
427	monitoring_activity_check	Appendix II - Monitoring Activities	descriptive																																																																								
428	monitoring_visit_log	Appendix III- Monitoring Visit Log	descriptive																																																																								
429	delegation_log	Appendix IV - Delegation Log	descriptive																																																																								
430	monitoring_report	Appendix V - monitoring Report template	descriptive																																																																								

431	cto_monitoring_documents_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete				
0	Incomplete												
1	Unverified												
2	Complete												
Instrument: <b>CTO MOPH Approval</b> (cto_moph_approval)			<a href="#">^ Collapse</a>										
432	cto_moph_approval	Here you upload the MOPH approval letter	descriptive										
433	upload_moph_letter	Upload approval Letter	file										
434	moph_approval_date	Approval Date	text (date_dmy)										
435	comment_moph_letter	Comment	text										
436	cto_moph_approval_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete				
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Instrument: <b>General Information Clinical Trial</b> (general_information_clinical_trial)			<a href="#">^ Collapse</a>										
437	trial_info	Please add in this section more information about the Trial	descriptive										
438	sponsor_trial	Section Header: <i>Sponsor</i> Please select the sponsor of the study	radio <table border="1"> <tr><td>1</td><td>Sidra PI</td></tr> <tr><td>2</td><td>External Sponsor (Pharma)</td></tr> <tr><td>3</td><td>External Sponsor (Academia)</td></tr> <tr><td>4</td><td>External Sponsor (Hospital)</td></tr> <tr><td>5</td><td>other</td></tr> </table>	1	Sidra PI	2	External Sponsor (Pharma)	3	External Sponsor (Academia)	4	External Sponsor (Hospital)	5	other
1	Sidra PI												
2	External Sponsor (Pharma)												
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4	External Sponsor (Hospital)												
5	other												
439	other_sponsor Show the field ONLY if: [sponsor_trial] = '5'	Other:	text										
440	insurance_cto	Section Header: <i>Insurance</i> Is there any insurance need?	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No						
1	Yes												
0	No												
441	policy_insurance Show the field ONLY if: [insurance_cto] = '1'	Upload the policy for the insurance	file										
442	cost_insurance Show the field ONLY if: [insurance_cto] = '1'	Cost of Insurance	text										
443	insurance_start Show the field ONLY if: [insurance_cto] = '1'	Insurance Start date	text (date_ymd)										
444	insurance_expiry_date Show the field ONLY if: [insurance_cto] = '1'	Insurance expiry date	text (date_ymd)										
445	contract_link	Section Header: <i>Contracts</i> Is there any contract with external partners? <i>if yes, check project for the links</i>	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No						
1	Yes												
0	No												
446	trial_budget_q	Section Header: <i>Budget</i> Is there a trial specific budget?	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No						
1	Yes												
0	No												
447	upload_trial_budget Show the field ONLY if: [trial_budget_q] = '1'	Upload the budget (template from CTO)	file										
448	budget_amount Show the field ONLY if: [trial_budget_q] = '1'	Total amount (in QAR): <i>in QAR</i>	text (number)										
449	amountperpatient Show the field ONLY if: [trial_budget_q] = '1'	Amount per patient (in QAR) <i>in QAR</i>	text (number)										

450	general_information_clinical_trial_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete								
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1	Unverified																
2	Complete																
Instrument: <b>CTO Monitoring Plan</b> (cto_monitoring_plan)			<a href="#">^ Collapse</a>														
451	explain_moniplan	In this section you can upload the Monitoring plan specific for this study.	descriptive														
452	uplod_moniplan	Upload Plan	file														
453	frequency_monivisit	Frequency of Monitoring Visits	dropdown (autocomplete) <table border="1"> <tr><td>1</td><td>weekly</td></tr> <tr><td>2</td><td>bi-weekly</td></tr> <tr><td>3</td><td>monthly</td></tr> <tr><td>4</td><td>bi-monthly</td></tr> <tr><td>5</td><td>quarterly</td></tr> <tr><td>6</td><td>every half year</td></tr> <tr><td>7</td><td>other</td></tr> </table>	1	weekly	2	bi-weekly	3	monthly	4	bi-monthly	5	quarterly	6	every half year	7	other
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2	bi-weekly																
3	monthly																
4	bi-monthly																
5	quarterly																
6	every half year																
7	other																
454	other_frequency Show the field ONLY if: [frequency_monivisit] = '7'	Other (please tell more)	text														
455	comment_moniplan	Comment	text														
456	cto_monitoring_plan_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete								
0	Incomplete																
1	Unverified																
2	Complete																
Instrument: <b>CTO Monitoring Visit Log</b> (cto_monitoring_visit_log)			<a href="#">^ Collapse</a>														
457	monitoring_visit_explain	Here you can upload a Monitoring Visit Log	descriptive														
458	cto_date_site_visit	Date of Site Visit	text (date_dmy)														
459	upload_monilog	Upload Monitoring Visit Log	file														
460	study_team_member	Please enter participating Study Team Member	dropdown (autocomplete) <table border="1"> <tr><td>1</td><td>add person dropdown</td></tr> </table>	1	add person dropdown												
1	add person dropdown																
461	comment_monivisit	Comment	text														
462	cto_monitoring_visit_log_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete								
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1	Unverified																
2	Complete																
Instrument: <b>CTO Monitoring Report Part 1</b> (cto_monitoring_report_part_1)			<a href="#">^ Collapse</a>														
463	explain_monireport	Appendix VMonitoring Report for Clinical Trial	descriptive														
464	upload_report	Upload Monitoring Report	file														
465	date_monitoring_report	Date	text (date_dmy)														
466	followup_report	Are there any issues to be followed up?	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No										
1	Yes																
0	No																
467	chose_date_to_solve Show the field ONLY if: [followup_report] = '1'	By which date it needs to be solved? <i>for several issues, chose closseset date</i>	text (date_dmy)														
468	comment_report	Comment	text														
469	cto_monitoring_report_part_1_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete								
0	Incomplete																
1	Unverified																
2	Complete																
Instrument: <b>CTO Monitoring Report Part 2 Issue register</b> (cto_monitoring_report_part_2_issue_register)			<a href="#">^ Collapse</a>														

470	cto_monitoring_report_part_2_issue_register_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete												
0	Incomplete																				
1	Unverified																				
2	Complete																				
Instrument: <b>CTO Issue log</b> (cto_issue_log)			<a href="#">^ Collapse</a>																		
471	cto_issue_title	Issue title	text Field Annotation: @HIDDEN																		
472	refer_to_report	Referring to the Monitoring Report from	text (date_dmy)																		
473	new_follow_up_issue	Is it a new or follow up issue?	radio <table border="1"> <tr><td>1</td><td>New Issue</td></tr> <tr><td>2</td><td>Follow-up Issue</td></tr> </table>	1	New Issue	2	Follow-up Issue														
1	New Issue																				
2	Follow-up Issue																				
474	cto_class_issue	Classification	radio <table border="1"> <tr><td>1</td><td>Minor</td></tr> <tr><td>2</td><td>Major</td></tr> <tr><td>3</td><td>Critical</td></tr> </table> Field Annotation: @HIDDEN	1	Minor	2	Major	3	Critical												
1	Minor																				
2	Major																				
3	Critical																				
475	cto_origin_issue	Origin of issue	radio <table border="1"> <tr><td>1</td><td>Protocol deviation</td></tr> <tr><td>2</td><td>found during inspection</td></tr> <tr><td>3</td><td>new policy</td></tr> </table> Field Annotation: @HIDDEN	1	Protocol deviation	2	found during inspection	3	new policy												
1	Protocol deviation																				
2	found during inspection																				
3	new policy																				
476	standard_issues	Category Issues	checkbox <table border="1"> <tr><td>1</td><td>standard_issues__1</td><td>ICF Issue</td></tr> <tr><td>2</td><td>standard_issues__2</td><td>Study Drug / Device issue</td></tr> <tr><td>3</td><td>standard_issues__3</td><td>Regulatory Issue</td></tr> <tr><td>4</td><td>standard_issues__4</td><td>Safety Reporting Issue</td></tr> <tr><td>5</td><td>standard_issues__5</td><td>Source data verification Issues</td></tr> <tr><td>6</td><td>standard_issues__6</td><td>Regulatory Binder Issue</td></tr> </table>	1	standard_issues__1	ICF Issue	2	standard_issues__2	Study Drug / Device issue	3	standard_issues__3	Regulatory Issue	4	standard_issues__4	Safety Reporting Issue	5	standard_issues__5	Source data verification Issues	6	standard_issues__6	Regulatory Binder Issue
1	standard_issues__1	ICF Issue																			
2	standard_issues__2	Study Drug / Device issue																			
3	standard_issues__3	Regulatory Issue																			
4	standard_issues__4	Safety Reporting Issue																			
5	standard_issues__5	Source data verification Issues																			
6	standard_issues__6	Regulatory Binder Issue																			
477	cto_issue_describe	Describe issue	notes																		
478	resolve_date	To be resolved by	text (date_dmy)																		
479	who_reposnible	who is responsible	text																		
480	cto_issue_log_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete												
0	Incomplete																				
1	Unverified																				
2	Complete																				
Instrument: <b>CTO Delegation of Authority Log</b> (cto_delegation_of_authority_log)			<a href="#">^ Collapse</a>																		
481	explain_delofautho	Here you can upload the Delegation of Authority Log	descriptive																		
482	upload_delofautho	Upload form, signed by PI	file																		
483	comment_delofautho	Comment	text																		
484	cto_delegation_of_authority_log_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete												
0	Incomplete																				
1	Unverified																				
2	Complete																				
Instrument: <b>IRBNet Import 16709Base</b> (irbnet_import_16709base)			<a href="#">^ Collapse</a>																		
485	project_id	Project ID	text																		
486	package_number	Package Number	text																		
487	multi_site_id	Multi-Site ID	text																		
488	irbnet_id	IRBNet ID	text																		
489	project_title	Project Title	text																		
490	pi_name	PI Name	text																		
491	document_id	Document ID	text																		

492	document_description	Document Description	text
493	last_updated	Last Updated	text
494	diff_order_pi_name	PI Name (other order)	text
495	pi_phone	PI Phone	text
496	pi_email	PI Email	text
497	pi_specialty	PI Specialty	text
498	pi_specialty_other	PI Specialty - Other	text
499	research_personnel	Research Personnel	text
500	sdr_number	SDR # (Sidra Unique Project Identifier, listed in IRBNet document)	text
501	investigator_initiated	Investigator Initiated	text
502	risk_level	Risk Level	text
503	tors_treatment_research	Type of Research Study (TORS)_Treatment Research	text
504	tors_prevention_research	Type of Research Study (TORS)_Prevention Research	text
505	tors_diagnostic_research	Type of Research Study_Diagnostic Research	text
506	tors_screening_research	Type of Research Study_Screening Research	text
507	tors_quality_of_life_research	Type of Research Study_Quality of Life Research	text
508	tors_genetic_study	Type of Research Study_Genetic Study	text
509	tors_precision_medicine	Type of Research Study_Precision Medicine	text
510	tors_epidemiological_study	Type of Research Study_Epidemiological Study	text
511	tors_data_repository_for_futur r	Type of Research Study_Data Repository for futur	text
512	tors_specimen_repository	Type of Research Study_Specimen repository	text
513	tors_comparative_research	Type of Research Study_Comparative Research	text
514	tors_supportive_care_researc h	Type of Research Study_Supportive Care Research	text
515	tors_chart_review_analys	Type of Research Study_Chart Review/ Data Analys	text
516	tors_analysis_of_existing_biol	Type of Research Study_Analysis of existing biol	text
517	tors_other1	Type of Research Study_Other	text
518	tors_other2	Type of Research Study - Other	text
519	rl_sidra_outpatient_clinics	Research Location_Sidra Outpatient Clinics	text
520	rl_specify_the_clinic_plai	Research Location_Specify the Clinic: (Plai	text
521	rl_sidra_regular_inpatient_w	Research Location_Sidra Regular Inpatient w	text
522	rl_specify_the_ward_plain	Research Location_Specify the ward: (Plain	text
523	rl_picu	Research Location_PICU	text
524	rl_nicu	Research Location_NICU	text
525	rl_pediatric_emergency_depar	Research Location_Pediatric Emergency Depar	text
526	rl_women_er_deptm	Research Location_Women's Emergency Departm	text
527	rl_operation_rooms	Research Location_Operation rooms	text
528	rl_pre_operative_areas	Research Location_Pre-operative areas	text
529	rl_post_operative_areas	Research Location_Post-operative areas	text
530	rl_icu	Research Location_ICU	text
531	rl_ccu	Research Location_CCU	text
532	rl_cardiac_cath_lab	Research Location_Cardiac Cath Lab	text
533	rl_research_labs	Research Location_Research labs	text
534	rl_clinical_laboratory_and_p	Research Location_Clinical Laboratory and P	text
535	rl_diagnostic_imaging	Research Location_Diagnostic Imaging	text
536	rl_physiotherapy	Research Location_Physiotherapy	text
537	rl_no_recruitment_sidra	Research Location_No recruitment at Sidra,	text
538	rl_other1	Research Location_Other	text
539	rl_other2	Research Location - Other	text
540	applicable_disease_sites	Applicable Disease Sites	text
541	overall_number_of_participan ts	Overall Number of Participants	text
542	number_participants_sidra_on ly	Number of Participants at Sidra Only	text

543	tp_adult_patients	Target Population_Adult patients	text
544	tp_adult_healthy_volunteers	Target Population_Adult healthy volunteers	text
545	tp_children_patients	Target Population_Children (patients)	text
546	tp_children_healthy_volunte	Target Population_Children (healthy volunte	text
547	tp_viable_neonates	Target Population_Viable neonates	text
548	tp_cognitively_impaired_subj	Target Population_Cognitively impaired subj	text
549	tp_prisoners	Target Population_Prisoners	text
550	tp_students	Target Population_Students	text
551	tp_sidra_medicine_employees	Target Population_Sidra Medicine employees	text
552	tp_pregnant_women_human_fet	Target Population_Pregnant women, human fet	text
553	tp_none_above	Target Population_None of the above. The st	text
554	procedures_admin_drug	Specify Research Procedures_Administration of a drug,	text
555	procedures_medical_device	Specify Research Procedures_Use of a medical device	text
556	procedures_coll_blood_sampl	Specify Research Procedures_Collection of blood sampl	text
557	procedures_pros_coll1	Specify Research Procedures_Pro prospective collection of	text
558	procedures_prosp_coll2	Specify Research Procedures_Pro prospective collection of	text
559	procedures_material	Specify Research Procedures_Research involving materi	text
560	procedures_records	Specify Research Procedures_Research involving the co	text
561	procedures_video	Specify Research Procedures_Collection of data from v	text
562	procedures_behaviour	Specify Research Procedures_Research on individual or	text
563	procedures_education	Specify Research Procedures_Research conducted in est	text
564	procedures_taste	Specify Research Procedures_Taste and food quality ev	text
565	procedures_other1	Specify Research Procedures_Other	text
566	procedures_other2	Research Procedures - Other	text
567	study_funded	Study Funded	text
568	funding_source1	Study Funding Not Applicable Explanation	text
569	company_name	Company Name	text
570	contact_person	Contact Person	text
571	company_phone	Company Phone Number	text
572	company_email	Company Email Address	text
573	multi_site	Multi-Site	text
574	lead_site_name	Lead Site Name	text
575	irb_approval_lead_site	IRB Approval	text
576	clinical_trial	Clinical Trial	text
577	clinical_trial_phase	Clinical Trial Phase	text
578	trial_phase_other	Clinical Trial Phase - Other	text
579	drugs_and_biologics	Drugs and Biologics	text
580	submission_new_drug_file	Submission of Investigational New Drug File	text
581	submission_new_drug_explain	Submission of Investigational New Drug - Expl	text
582	ind_imp_holder	IND/IMP Holder	text
583	medical_devices	Medical Devices	text
584	submission_of_ide	Submission of IDE	text
585	no_subm_ide_explain	No Submission of IDE Explanation	text
586	ide_ip_holder	IDE/IP Holder	text
587	device_risk_determ	Device Risk Determinations	text
588	device_risk_determ_other	Device Risk Determinations - Other	text
589	location_sidra_outpatient	Research Location - Sidra Outpatient	text
590	location_regular_patient	Research Location - Sidra Regular Patient	text
591	clinical_trial_posted	Clinical Trial Posted	text

592	irbnet_import_16709base_complete	Section Header: <i>Form Status</i> Complete?	<div>dropdown</div> <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								

Instrument: **IRBNet Import Active Projects** (irbnet\_import\_active\_projects)[^ Collapse](#)

593	id_from_irbnet	IRBNet ID	text						
594	title_active	Title	text						
595	pi_name_active	PI Name	text						
596	sponsor_active	Sponsor	text						
597	keywords_active	Keywords	text						
598	internal_ref_nu_active	Internal Reference Number	text						
599	submission_id_active	Submission ID	text						
600	board_ref_nu_active	Board Reference Number	text						
601	submitted_to_active	Submitted To	text						
602	first_sub_date_active	First Submission Date	text						
603	reviewed_by_active	Reviewed By	text						
604	first_sub_type_active	First Submission Type	text						
605	first_actual_review_active	First Actual Review Type	text						
606	first_agenda_date_active	First Agenda Date	text						
607	first_action_active	First Action	text						
608	first_eff_date_active	First Effective Date	text						
609	initial_approval_active	Initial Approval Date	text						
610	project_risk_level_active	Project Risk Level	text						
611	current_pro_status_active	Current Project Status	text						
612	expiration_date_active	Expiration Date	text						
613	next_report_due_active	Next Report Due	text						
614	irbnet_import_active_projects_complete	Section Header: <i>Form Status</i> Complete?	<div>dropdown</div> <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								

Instrument: **IRBNet Import People** (irbnet\_import\_people)[^ Collapse](#)

615	project_id_ppl	Project ID	text	
616	deleted_evt	Person has been removed from IRB protocol, click if applicable.	radio <div><div>1</div><div>Removed</div></div>	
617	corrected_email	Corrected email for Lookup	text	
618	concat_field	concatenated field for identification	text	
619	package_number_ppl	Package Number	text	
620	multi_site_id_ppl	Multi-Site ID	text	
621	irbnet_id_ppl	IRBNet ID	text	
622	project_title_ppl	Project Title	text	
623	pi_name_ppl	PI Name	text	
624	document_id_ppl	Document ID	text	
625	document_description_ppl	Document Description	text	
626	last_updated_ppl	Last Updated	text	
627	research_person_info_ppl	Research Personnel Information #	text	
628	affiliation_ppl	Institution Affiliation	text	
629	affiliation_other_ppl	Institution Affiliation - Other Institution	text	
630	first_name_ppl	First Name	text	
631	last_name_ppl	Last Name	text	
632	degree_ppl	Degree	text	
633	phone_number_ppl	Phone Number	text	
634	email_address_ppl	Email Address	text	
635	research_role_ppl	Research Role	text	



636	role_other_ppl	Research Role - Other	text
637	responsibility_1_ppl	Responsibilities_Obtain data through communications or interpersonal contact "interaction"	text
638	responsibility_2_ppl	Responsibilities_Obtain data through physical procedures or manipulation of the individual or the individual's environment "intervention"	text
639	responsibility_3_ppl	Responsibilities_Obtain informed consent	text
640	responsibility_4_ppl	Responsibilities_Obtain private identifiable data/samples about human subjects (Obtain: record, use, study, or analyze)	text
641	responsibility_5_ppl	Responsibilities_Access Subjects medical records	text
642	responsibility_6_ppl	Responsibilities_Other: Extraction of allele frequency data from QGP (de-identified data)	text
643	responsibility_6a_ppl	Responsibilities - Other (give details)	text
644	training_completion_ppl	Training Completion	text
645	doi_ppl	Research Related Declarations	text
646	irbnet_import_people_complete	Section Header: <i>Form Status</i> Complete?	dropdown
			0   Incomplete
			1   Unverified
			2   Complete

Instrument: **IRBNet Manual Import FundingSource** (irbnet\_manual\_import\_fundingsource)[^ Collapse](#)

647	irb_id_report	IRBNet Number from report	text
648	package_number_funds	Package Number	text
649	last_updated_funds	Last Updated	text
650	project_funding_info	Project Funding Source	text
651	grant_title	Grant title	text
652	grant_pi_name	Grant PI Name	text
653	grant_reference	Grant ID/Funding Reference ID	text
654	irbnet_manual_import_fundingsource_complete	Section Header: <i>Form Status</i>  Complete?	dropdown
			0   Incomplete
			1   Unverified
			2   Complete

Instrument: **IRBNet Manual Import Collaborations** (irbnet\_manual\_import\_collaborations)[^ Collapse](#)

655	coll_site_name	Collaborator Site Name	text
656	site_contact_person	Site Contact Person	text
657	site_phone	Contact Person Phone Number	text
658	site_email	Contact Person Email Address	text
659	irb_review_justification	IRB Review Justification	text

660	site_person_active_in	Employees of this site do:	checkbox																		
			<table border="1"> <tr> <td>1</td> <td>site_person_active_in__1</td> <td>Employees of this site will intervene for research purposes with human subjects of the research by performing invasive or noninvasive procedures.</td> </tr> <tr> <td>2</td> <td>site_person_active_in__2</td> <td>Employees of this site will intervene for research purposes with human subjects of the research by manipulating the environment.</td> </tr> <tr> <td>3</td> <td>site_person_active_in__3</td> <td>Employees of this site will interact for research purposes with human subjects of the research.</td> </tr> <tr> <td>4</td> <td>site_person_active_in__4</td> <td>Employees of this site will obtain the informed consent of human subjects for the research.</td> </tr> <tr> <td>5</td> <td>site_person_active_in__5</td> <td>Employees of this site will obtain (record/use/study/analyze for research purposes identifiable private information or identifiable biological specimens from any source for the research</td> </tr> <tr> <td>6</td> <td>site_person_active_in__6</td> <td>Other</td> </tr> </table>	1	site_person_active_in__1	Employees of this site will intervene for research purposes with human subjects of the research by performing invasive or noninvasive procedures.	2	site_person_active_in__2	Employees of this site will intervene for research purposes with human subjects of the research by manipulating the environment.	3	site_person_active_in__3	Employees of this site will interact for research purposes with human subjects of the research.	4	site_person_active_in__4	Employees of this site will obtain the informed consent of human subjects for the research.	5	site_person_active_in__5	Employees of this site will obtain (record/use/study/analyze for research purposes identifiable private information or identifiable biological specimens from any source for the research	6	site_person_active_in__6	Other
1	site_person_active_in__1	Employees of this site will intervene for research purposes with human subjects of the research by performing invasive or noninvasive procedures.																			
2	site_person_active_in__2	Employees of this site will intervene for research purposes with human subjects of the research by manipulating the environment.																			
3	site_person_active_in__3	Employees of this site will interact for research purposes with human subjects of the research.																			
4	site_person_active_in__4	Employees of this site will obtain the informed consent of human subjects for the research.																			
5	site_person_active_in__5	Employees of this site will obtain (record/use/study/analyze for research purposes identifiable private information or identifiable biological specimens from any source for the research																			
6	site_person_active_in__6	Other																			
661	other_interaction	define other	text																		
662	irbnet_manual_import_collaborations_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete												
0	Incomplete																				
1	Unverified																				
2	Complete																				
Instrument: <b>IRBNet Import DrugsApplied</b> (irbnet_import_drugsapplied) <a href="#">^ Collapse</a>																					
663	drug_info	Drugs and Biologics Information #	text																		
664	generic_name	Generic Name	text																		
665	brand_name	Brand Name	text																		
666	marketing_authorization	Marketing Authorization	text																		
667	used_accordingly	Drug/Biologic Used Accordingly	text																		
668	use_explanation	Drug Use Explanation	text																		
669	irbnet_import_drugsapplied_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete												
0	Incomplete																				
1	Unverified																				
2	Complete																				
Instrument: <b>IRBNet Import MedicalDevices</b> (irbnet_import_medicaldevices) <a href="#">^ Collapse</a>																					
670	device_info	Medical Devices Information #	text																		
671	device_name	Device Name	text																		
672	market_authoriz_device	Device Marketing Authorization	text																		
673	device_in_study	Device in Research Study	text																		
674	explanation_study	Device in Research Study Explanation	text																		
675	irbnet_import_medicaldevices_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete												
0	Incomplete																				
1	Unverified																				
2	Complete																				
Instrument: <b>IRB-408-A Modification Form - For Research Personnel Change</b> (irb408a_modification_form_for_research_personnel_c) <a href="#">^ Collapse</a>																					
676	modification	Modification Date:	text (date_dmy), Required																		

677	info	<p>1. Information</p> <p>To change research personnel whether to add or to remove members from your study, submit the following:</p> <ol style="list-style-type: none"> <li>1. Modification Form IRB-408-A.</li> <li>2. Modified Main Study Application</li> </ol> <ul style="list-style-type: none"> <li>• Update section II of your current approved version of the main study application</li> <li>• This Modification should take place through IRBNET</li> </ul>	descriptive								
678	study_status	<p>2. Current Study Status</p> <p>Check one option:</p>	<p>radio, Required</p> <table border="1"> <tr> <td>1</td> <td>The research study has not started (no subjects have consented)</td> </tr> <tr> <td>2</td> <td>Subjects are currently enrolled</td> </tr> <tr> <td>3</td> <td>The research study is permanently closed to subject enrollments but research related procedures, interactions or interventions including long term follow up are ongoing</td> </tr> <tr> <td>4</td> <td>All research related procedures, interactions or interventions are completed. The research study is open to analysis of private identifiable information</td> </tr> </table>	1	The research study has not started (no subjects have consented)	2	Subjects are currently enrolled	3	The research study is permanently closed to subject enrollments but research related procedures, interactions or interventions including long term follow up are ongoing	4	All research related procedures, interactions or interventions are completed. The research study is open to analysis of private identifiable information
1	The research study has not started (no subjects have consented)										
2	Subjects are currently enrolled										
3	The research study is permanently closed to subject enrollments but research related procedures, interactions or interventions including long term follow up are ongoing										
4	All research related procedures, interactions or interventions are completed. The research study is open to analysis of private identifiable information										
679	personnel_changes	<p>3. Personnel Change</p> <p>Check what is applicable:</p>	<p>checkbox, Required</p> <table border="1"> <tr> <td>1</td> <td>personnel_changes__1</td> <td>Removing personnel</td> </tr> <tr> <td>2</td> <td>personnel_changes__2</td> <td>Adding personnel</td> </tr> </table>	1	personnel_changes__1	Removing personnel	2	personnel_changes__2	Adding personnel		
1	personnel_changes__1	Removing personnel									
2	personnel_changes__2	Adding personnel									
680	removing_personnel Show the field ONLY if: [personnel_changes(1)] = '1'	Does the change require revision to study documents?	<p>dropdown, Required</p> <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>2</td> <td>No</td> </tr> </table>	1	Yes	2	No				
1	Yes										
2	No										
681	revised_doc Show the field ONLY if: [removing_personnel] = '1'	<p>If yes, list the revised documents:</p> <p>Type/write document(s) name(s):</p>	text								
682	personnel_names Show the field ONLY if: [removing_personnel] = '1'	List names of personnel who left the study:	text								
683	revision_to_study_doc Show the field ONLY if: [personnel_changes(2)] = '1'	Does the change require revisions to study documents?	<p>dropdown, Required</p> <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>2</td> <td>No</td> </tr> </table>	1	Yes	2	No				
1	Yes										
2	No										
684	yes_revised Show the field ONLY if: [revision_to_study_doc] = '1'	<p>If yes, list the revised documents:</p> <p>Type/write document(s) name(s):</p>	text								
685	personnel_added_to_study_2 Show the field ONLY if: [revision_to_study_doc] = '1'	List names of personnel added to the study:	text								
686	attestation	<p>4. Principal Investigator (PI) Attestation</p> <p>By submitting this form, the PI attests to comply with Sidra Medicine policies and procedures.</p>	descriptive								
687	irb408a_modification_form_for_research_personnel_complete	<p>Section Header: <i>Form Status</i></p> <p>Complete?</p>	<p>dropdown</p> <table border="1"> <tr> <td>0</td> <td>Incomplete</td> </tr> <tr> <td>1</td> <td>Unverified</td> </tr> <tr> <td>2</td> <td>Complete</td> </tr> </table>	0	Incomplete	1	Unverified	2	Complete		
0	Incomplete										
1	Unverified										
2	Complete										
<p>Instrument: <b>IRB-408-B- Modification Form - Research Study</b> (irb408b_modification_form_research_study) <a href="#">^ Collapse</a></p>											
688	modification_date	Modification Date:	text (date_dmy), Required								
689	info2	<p>1. Information</p> <p>Attach the following:</p> <ol style="list-style-type: none"> <li>1. Modification Form IRB-408-B.</li> <li>2. Modified Main Study Application</li> </ol> <ul style="list-style-type: none"> <li>• Update the appropriate section of your current approved version of the main study application (if applicable)</li> <li>• This Modification should take place through IRBNET</li> </ul>	descriptive								

690	modified_materials	2. Modified Materials	checkbox, Required																														
			<table border="1"> <tr> <td>1</td> <td>modified_materials__1</td> <td>Protocol</td> </tr> <tr> <td>2</td> <td>modified_materials__2</td> <td>IRB-400/401 (English/Arabic) Informed Consent Form</td> </tr> <tr> <td>3</td> <td>modified_materials__3</td> <td>IRB-402/403 (English/Arabic) Parental Permission Form</td> </tr> <tr> <td>4</td> <td>modified_materials__4</td> <td>IRB-404/405 (English/Arabic) Assent Form (Child)</td> </tr> <tr> <td>5</td> <td>modified_materials__5</td> <td>Flyer, Advertisement</td> </tr> <tr> <td>6</td> <td>modified_materials__6</td> <td>Questionnaire</td> </tr> <tr> <td>7</td> <td>modified_materials__7</td> <td>Investigator Brochure</td> </tr> <tr> <td>8</td> <td>modified_materials__8</td> <td>Letter to Investigators</td> </tr> <tr> <td>9</td> <td>modified_materials__9</td> <td>Risk Information</td> </tr> <tr> <td>20</td> <td>modified_materials__20</td> <td>Other</td> </tr> </table>	1	modified_materials__1	Protocol	2	modified_materials__2	IRB-400/401 (English/Arabic) Informed Consent Form	3	modified_materials__3	IRB-402/403 (English/Arabic) Parental Permission Form	4	modified_materials__4	IRB-404/405 (English/Arabic) Assent Form (Child)	5	modified_materials__5	Flyer, Advertisement	6	modified_materials__6	Questionnaire	7	modified_materials__7	Investigator Brochure	8	modified_materials__8	Letter to Investigators	9	modified_materials__9	Risk Information	20	modified_materials__20	Other
1	modified_materials__1	Protocol																															
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7	modified_materials__7	Investigator Brochure																															
8	modified_materials__8	Letter to Investigators																															
9	modified_materials__9	Risk Information																															
20	modified_materials__20	Other																															
691	ifother Show the field ONLY if: [modified_materials(20)] = '1'	If other, please specify.	text																														
692	study_status2	3. Current Study Status	radio																														
			<table border="1"> <tr> <td>1</td> <td>The research study has not started (no subjects have consented)</td> </tr> <tr> <td>2</td> <td>Subjects are currently enrolled</td> </tr> <tr> <td>3</td> <td>The research study is permanently closed to subject enrollments but research related procedures, interactions or interventions including long term follow up are ongoing</td> </tr> <tr> <td>4</td> <td>All research related procedures, interactions or interventions are completed. The research study is open to analysis of private identifiable information</td> </tr> </table>	1	The research study has not started (no subjects have consented)	2	Subjects are currently enrolled	3	The research study is permanently closed to subject enrollments but research related procedures, interactions or interventions including long term follow up are ongoing	4	All research related procedures, interactions or interventions are completed. The research study is open to analysis of private identifiable information																						
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693	summary	4. Modifications Summary  Provide a summary of the modifications and explain the rationale/justification for the change	text																														
694	re_consenting	5. Subjects notifications and re-consenting  Fill this section for modifications affecting the informed consent and subject participation. Check one option:	radio																														
			<table border="1"> <tr> <td>1</td> <td>Not applicable - no subjects enrolled</td> </tr> <tr> <td>2</td> <td>Re-consenting all subjects</td> </tr> <tr> <td>3</td> <td>Re-consenting selected number of subjects</td> </tr> </table>	1	Not applicable - no subjects enrolled	2	Re-consenting all subjects	3	Re-consenting selected number of subjects																								
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2	Re-consenting all subjects																																
3	Re-consenting selected number of subjects																																
695	if_re_consenting Show the field ONLY if: [re_consenting] = '3'	Type/write name	text																														
696	explanation	Type/write explanation of the rationale for the chosen selection above:	text																														
697	current_enrollment	Current enrollment at Sidra Medicine (single recruitment site)	descriptive																														
698	number_subjects	• Number of enrolled subjects:	text (number)																														
699	number_subjects_research	• Number of subjects who completed the research:	text (number)																														
700	multi_site_study	Current enrollment study wide (multi-site study)	descriptive																														
701	number_subjects2	• Number of enrolled subjects:	text (number)																														
702	number_research2	• Number of subjects who completed the research:	text (number)																														
703	pi_attestation	6. Principal Investigator (PI) Attestation  By submitting this form, the PI attests to comply with Sidra Medicine policies and procedures.	descriptive																														

704	irb408b_modification_form_research_study_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr> <td>0</td> <td>Incomplete</td> </tr> <tr> <td>1</td> <td>Unverified</td> </tr> <tr> <td>2</td> <td>Complete</td> </tr> </table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: <b>IRB-412-Closure Report Form</b> (irb412_closure_report_form)			<a href="#">^ Collapse</a>						
705	study_title	Study Title: [title_of_irb]	text Field Annotation: @READONLY						
706	irb_number	IRB Number: [irbnetnumber]	text Field Annotation: @READONLY						
707	sdr_number1	SDR Number: [projects]	text Field Annotation: @READONLY						
708	ipi	Principal Investigator: [ipi_irb]	text Field Annotation: @READONLY						
709	submission_date	Submission Date:	text (date_dmy), Required						
710	i_reason_for_closure	Section Header: <i>IRB 412- Instructions: Submit this form when you would like to request closure of your research study and provide a final report to the IRB.</i>  I. REASON FOR CLOSURE Check one option.	radio, Required <table border="1"> <tr> <td>1</td> <td>The study is complete</td> </tr> <tr> <td>2</td> <td>The study is cancelled (No work has been initiated, no data or samples have been collected)</td> </tr> <tr> <td>3</td> <td>Others</td> </tr> </table>	1	The study is complete	2	The study is cancelled (No work has been initiated, no data or samples have been collected)	3	Others
1	The study is complete								
2	The study is cancelled (No work has been initiated, no data or samples have been collected)								
3	Others								

711	confirm_completion_of_all Show the field ONLY if: [i_reason_for_closure] = '1'	Confirm completion of all the below. All boxes must be checked for appropriate closure:	checkbox	
			1	confirm_completion_of_all__1 All Subjects' recruitment & enrollment is complete. All research-related procedures, interactions or interventions including long term follow up is complete.
			2	confirm_completion_of_all__2 Obtaining private identifiable information (data, specimens) is complete. (Private identifiable information can be direct (data having direct identifier like subject name, hospital record # or other identifiers, etc.) or indirect (coded data that can be linked to direct identifiers and data by investigator(s)). The term investigator includes anyone involved in conducting this research).
			3	confirm_completion_of_all__3 Analyses of private identifiable information (data, specimens) are complete.
			4	confirm_completion_of_all__4 Further use or access to private identifiable information (data, specimens) is no longer needed (for example, manuscript writing, review of source documents by Sponsor ...etc.)
712	reason_cancel Show the field ONLY if: [i_reason_for_closure] = '2'	State the reason(s) of cancellation:	text, Required	
713	explain Show the field ONLY if: [i_reason_for_closure] = '3'	Explain:	text, Required	
714	ii_c_for_studies_funded_by	II. C. FOR STUDIES FUNDED BY EXTERNAL ENTITIES (example: Industry, Foundation ...etc.)	descriptive	

715	funding_entity	Has the funding entity completed the closeout visit?	radio, Required <table><tr><td>1</td><td>Yes (Provide a copy of the closeout visit letter) *If there are outstanding queries from the closeout visit, closure with the IRB is not appropriate</td></tr><tr><td>2</td><td>0 No (provide clarification or support letter from the sponsor indicating that no closeout visit will be conducted) *If closeout visit will be scheduled, closure with the IRB is not appropriate.</td></tr></table>	1	Yes (Provide a copy of the closeout visit letter) *If there are outstanding queries from the closeout visit, closure with the IRB is not appropriate	2	0 No (provide clarification or support letter from the sponsor indicating that no closeout visit will be conducted) *If closeout visit will be scheduled, closure with the IRB is not appropriate.
1	Yes (Provide a copy of the closeout visit letter) *If there are outstanding queries from the closeout visit, closure with the IRB is not appropriate						
2	0 No (provide clarification or support letter from the sponsor indicating that no closeout visit will be conducted) *If closeout visit will be scheduled, closure with the IRB is not appropriate.						
716	clarification Show the field ONLY if: [funding_entity] = '1' or [funding_entity] = '2'	Clarification:	text				
717	external_entity	Does a final report have to be submitted to the external entity?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
718	clarification2 Show the field ONLY if: [external_entity] = '1' or [external_entity] = '0'	Clarification:	text				
719	external_entity2	Has this final report submitted to the external entity?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
720	whom Show the field ONLY if: [external_entity2] = '1'	If yes, please specify to whom:	text, Required				
721	iii_subjects_accrual_status	III. SUBJECTS ACCRUAL STATUS SINCE LAST CONTINUING REVIEW Respond to the below for subjects enrolled at Sidra only.	descriptive				
722	number_of_enrolled_subject	Number of enrolled Subjects  (# of subjects who signed ICF. For research with waiver of IC, # of subjects who are included; or # of samples/records)	text (number), Required				
723	recruitment_finished_date	Recruitment Finished: Date Last participant was consented.	text (date_dmy), Required				
724	date_of_last_visit_or_contact	Date of last visit or contact with subject for research purposes	text (date_dmy)				
725	study_activities_are_suspended	Study activities are SUSPENDED, provide date of suspension:	text (date_dmy)				
726	date_subject_enrollment_was_opened	Date Subject Enrollment was opened.	text (date_dmy)				
727	date_subject_enrollment_was_closed	Date Subject Enrollment was closed.	text (date_dmy)				
728	withdrawals	Were there any Subjects' withdrawals?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
729	withdrew2 Show the field ONLY if: [withdrawals] = '1'	Number of subjects who withdrew.	text (number)				
730	provide_the_reason Show the field ONLY if: [withdrawals] = '1'	Provide the reason (s) for withdrawal.	text				
731	did_you_discontinue	Did you discontinue any Subject 's participation? (PI /team stopped subject participation early before reaching the study endpoint)	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
732	number_of_discontinuations Show the field ONLY if: [did_you_discontinue] = '1'	Number of discontinuations:	text (number)				
733	provide_the_reason_s_for_discontinuing_subjects_participation Show the field ONLY if: [did_you_discontinue] = '1'	Provide the reason (s) for discontinuing Subjects participation:	text				
734	signed_informed_consent	Please attach to this report a copy of last signed Informed Consent Form and/or signed Assent form (after hiding subject's details)	file Field Annotation: @HIDDEN				

735	please_upload_on_irbnet_th	Please upload on IRBNet the copy of last signed Informed Consent Form and/or signed Assent form (after hiding subject's details)	descriptive
736	iv_summary_of_the_research	IV. SUMMARY OF THE RESEARCH FINDINGS Provide a summary of your research study findings. List all publications resulting from the study	notes
737	v_adverse_events_ae_summar	V. Adverse Events (AE) Summarize all AEs that took place since last continuing review. The below is applicable to Sidra Site and any other site relying on Sidra IRB	descriptive
738	date_of_event_1	Date of event 1:	text (date_dmy)
739	description_of_the_event1 Show the field ONLY if: [date_of_event_1] = "	Description of the event and its management	text
740	date_of_the_event_2	Date of the event 2:	text (date_dmy)
741	description_of_the_event2 Show the field ONLY if: [date_of_the_event_2] = "	Description of the event and its management	text
742	date_of_the_event_3	Date of the event 3:	text (date_dmy)
743	description_of_the_event3 Show the field ONLY if: [date_of_the_event_3] = "	Description of the event and its management	text
744	date_of_the_event4	Date of the event 4:	text (date_dmy)
745	description_of_the_event4 Show the field ONLY if: [date_of_the_event4] = "	Description of the event and its management	text
746	if_no_aes_took_place_since	If no AEs took place since last continuing review, confirm by checking the below box:	radio 1 Confirmed
747	vi_deviations_summarize_al	VI. Deviations Summarize all deviations that took place since last continuing review. The below is applicable to Sidra Site and any other site relying on Sidra IRB	descriptive
748	date_of_the_event_a	Date of the event 1:	text (date_dmy)
749	description_of_the_event_a Show the field ONLY if: [date_of_the_event_a] = "	Description of the event	text
750	correction_action_s_a Show the field ONLY if: [description_of_the_event_a] = "	Correction action(s)	text
751	date_of_the_event_b	Date of the event 2:	text (date_dmy)
752	description_of_the_event_b Show the field ONLY if: [date_of_the_event_b] = "	Description of the event	text
753	correction_action_s_b Show the field ONLY if: [description_of_the_event_b] = "	Correction action(s)	text
754	date_of_the_event_c	Date of the event 3:	text (date_dmy)
755	description_of_the_event_c Show the field ONLY if: [date_of_the_event_c] = "	Description of the event	text
756	correction_action_s_c Show the field ONLY if: [description_of_the_event_c] = "	Correction action(s)	text
757	date_of_the_event_d	Date of the event 4:	text (date_dmy)
758	description_of_the_event_d Show the field ONLY if: [date_of_the_event_d] = "	Description of the event	text



759	correction_action_s_d Show the field ONLY if: [description_of_the_event_d] = "	Correction action(s)	text
760	if_no_deviations_took_plac	If no Deviations took place since last continuing review, confirm by checking the below box:	radio 1 Confirmed
761	vii_unanticipated_problems	VII. Unanticipated Problems Involving Risks to Subjects and Others Summarize all unanticipated problems involving risks that took place since last continuing review. The below is applicable to all study sites.	descriptive
762	date_of_the_event_e	Date of the event 1:	text (date_dmy)
763	description_of_the_event_e Show the field ONLY if: [date_of_the_event_e] = "	Description of the event and its management	text
764	were_changes_to_the_study Show the field ONLY if: [description_of_the_event_e] = "	Were changes to the study materials needed?	yesno 1 Yes 0 No
765	explain_e Show the field ONLY if: [were_changes_to_the_study] = '1'	explain:	text
766	for_serious_continuous_e Show the field ONLY if: [description_of_the_event_e] = "	For serious/continuous noncompliance, describe the corrective actions:	text
767	date_of_the_event_f	Date of the event 2:	text (date_dmy)
768	description_of_the_event_f Show the field ONLY if: [date_of_the_event_f] = "	Description of the event and its management	text
769	were_changes_to_f Show the field ONLY if: [description_of_the_event_f] = "	Were changes to the study materials needed?	yesno 1 Yes 0 No
770	explain_f Show the field ONLY if: [were_changes_to_f] = '1'	explain:	text
771	for_serious_continuous_f Show the field ONLY if: [description_of_the_event_f] = "	For serious/continuous noncompliance, describe the corrective actions:	text
772	date_of_the_event_g	Date of the event 3:	text (date_dmy)
773	description_of_the_event_g Show the field ONLY if: [date_of_the_event_g] = "	Description of the event and its management	text
774	were_changes_to_g Show the field ONLY if: [description_of_the_event_g] = "	Were changes to the study materials needed?	yesno 1 Yes 0 No
775	explain_g Show the field ONLY if: [were_changes_to_g] = '1'	explain:	text
776	for_serious_g Show the field ONLY if: [description_of_the_event_g] = "	For serious/continuous noncompliance, describe the corrective actions:	text
777	date_of_the_event_h	Date of the event 4:	text (date_dmy)
778	description_of_the_event_h Show the field ONLY if: [description_of_the_event_g] = "	Description of the event and its management	text

779	were_changes_h Show the field ONLY if: [description_of_the_event_h] = ""	Were changes to the study materials needed?	yesno 1 Yes 0 No
780	explain_h Show the field ONLY if: [were_changes_h] = '1'	explain:	text
781	for_serious_h Show the field ONLY if: [description_of_the_event_h] = ""	For serious/continuous noncompliance, describe the corrective actions:	text
782	were_all_the_above_unantic	Were all the above unanticipated problems promptly reported to the IRB?	yesno 1 Yes 0 No
783	justify_below_fill_in_irb Show the field ONLY if: [were_all_the_above_unantic] = '0'	Justify below & fill in IRB-411 form.	text
784	if_no_up_took_place_since	If no UP took place since last continuing review, confirm by checking the below box.	radio 1 Confirmed
785	viii_update_since_last_con	VIII. Update Since Last Continuing Review The below is applicable to all study sites.	descriptive
786	did_you_receive_any_subjec	Did you receive any subject's complaint about the study?	yesno 1 Yes 0 No
787	describe_the_subject Show the field ONLY if: [did_you_receive_any_subjec] = '1'	describe the subject complaint and how it was managed.	text
788	are_you_aware_of_any	Are you aware of any new risk or benefit related to the study not previously reported to the IRB?	yesno 1 Yes 0 No
789	explain_yes Show the field ONLY if: [are_you_aware_of_any] = '1'	Explain	text
790	are_you_aware_of_any_probl	Are you aware of any problems that require prompt reporting to the IRB not previously reported to the IRB?	yesno 1 Yes 0 No
791	explain_yes2 Show the field ONLY if: [are_you_aware_of_any_probl] = '1'	Explain	text
792	are_you_aware_of_any_modif	Are you aware of any modifications to the study materials not previously reported to the IRB?	yesno 1 Yes 0 No
793	explain_yes3 Show the field ONLY if: [are_you_aware_of_any_modif] = '1'	Explain	text
794	ix_supplemental_reports_si	IX. SUPPLEMENTAL REPORTS SINCE LAST CONTINUING REVIEW Submit the below items as applicable or any other reports relevant to the risks or potential benefits of the study	descriptive
795	scientific_publications_re	Scientific publications relevant to the risks or potential benefits of the study	dropdown 1 Available 2 Not available 3 Not applicable
796	copy_attached Show the field ONLY if: [scientific_publications_re] = '1'	Copy attached.	file

797	<div>explain_not</div> <div>Show the field ONLY if: [scientific_publications_re] = '2'</div>	Explain:	text						
798	<div>data_safety_monitoring_rep</div>	Data Safety monitoring Report	<div>dropdown</div> <table><tr><td>1</td><td>Available</td></tr><tr><td>2</td><td>Not available</td></tr><tr><td>3</td><td>Not applicable</td></tr></table>	1	Available	2	Not available	3	Not applicable
1	Available								
2	Not available								
3	Not applicable								
799	<div>copy_attached2</div> <div>Show the field ONLY if: [data_safety_monitoring_rep] = '1'</div>	Copy attached	file						
800	<div>explain_not2</div> <div>Show the field ONLY if: [data_safety_monitoring_rep] = '2'</div>	Explain:	text						
801	<div>frequency_of_dsmb_dmc_revi</div> <div>Show the field ONLY if: [data_safety_monitoring_rep] = '2'</div>	Frequency of DSMB/DMC Review:	text						
802	<div>expected_date_of_next_repo</div> <div>Show the field ONLY if: [data_safety_monitoring_rep] = '2'</div>	Expected Date of next report:	text (date_dmy)						
803	<div>is_there_any_change_to_the</div> <div>Show the field ONLY if: [data_safety_monitoring_rep] = '2'</div>	Is there any change to the Monitoring plan:	text						
804	<div>study_follow_up</div>	Study Monitoring Report or Follow up Letter / Audit Report	<div>dropdown</div> <table><tr><td>1</td><td>Available</td></tr><tr><td>2</td><td>Not available</td></tr><tr><td>3</td><td>Not applicable</td></tr></table>	1	Available	2	Not available	3	Not applicable
1	Available								
2	Not available								
3	Not applicable								
805	<div>copy_attached3</div> <div>Show the field ONLY if: [study_follow_up] = '1'</div>	Copy attached	file						
806	<div>explain3</div> <div>Show the field ONLY if: [study_follow_up] = '2'</div>	Explain	text						
807	<div>interim_findings</div>	Interim findings	<div>dropdown</div> <table><tr><td>1</td><td>Available</td></tr><tr><td>2</td><td>Not available</td></tr><tr><td>3</td><td>Not applicable</td></tr></table>	1	Available	2	Not available	3	Not applicable
1	Available								
2	Not available								
3	Not applicable								
808	<div>copy_attached4</div> <div>Show the field ONLY if: [interim_findings] = '1'</div>	Copy attached.	file						
809	<div>explain4</div> <div>Show the field ONLY if: [interim_findings] = '2'</div>	Explain	text						
810	<div>multi_center_trial_reports</div>	Multi- center trial reports	<div>dropdown</div> <table><tr><td>1</td><td>Available</td></tr><tr><td>2</td><td>Not available</td></tr><tr><td>3</td><td>Not applicable</td></tr></table>	1	Available	2	Not available	3	Not applicable
1	Available								
2	Not available								
3	Not applicable								
811	<div>copy_attached5</div> <div>Show the field ONLY if: [multi_center_trial_reports] = '1'</div>	Copy attached	file						
812	<div>explain5</div> <div>Show the field ONLY if: [multi_center_trial_reports] = '2'</div>	Explain	text						

^ Collapse

840	ethical_issues_patient_s_r	Ethical Issues (Patient's rights & Safety, consent forms- has patients will be protected, adverse event users' involvement in design)	text						
841	data_security_confidential	Data – Security: (Confidentiality of patient data)	text						
842	confidentiality_of_patient	Confidentiality of Patient Data: (Describe procedures for maintaining participant confidentiality and/or anonymity, especially if tape recording, photographs, movies or videotapes will be used.1. Privacy: Address how the privacy of individuals or groups will be maintained (e.g. , how participants will be afforded privacy while participating in research activities).2. Confidentiality: How will the confidentiality of data be ensured? Outline all of the precautions that will be used to maintain the confidentiality of identifiable information.	text						
843	timetable_realistic_projec	Timetable: (Realistic project schedule- Study plan showing flow chart of orders, timing & site of procedures)	text						
844	references_list_of_all_cit	References: List of all citation mentioned within the proposal	text						
845	budgeting_provide_detail_b	Budgeting: (Provide detail budget for each research and each core unit in their respective section of the application. Incorporate a detailed budget for all requested support for the first year)	text						
846	principal_investigator_sta	Principal Investigator Statement of Compliance:I understand and accept responsibility for ensuring the safety and welfare of all human subjects who participate in the proposed research project. I certify that all key personnel, including myself, sub/co-investigators, research coordinators, trainees, and students have completed the SIDRA required training on human subjects' protection. I agree to a continuing exchange of information with the SIDRA IRB including the requirements to (i) obtain IRB approval before making non-emergency changes/revisions to the project, except where necessary to eliminate apparent immediate hazards to subjects or others, (ii) provide progress reports to the SIDRA IRB at their request (and at least annually), and (iii) report promptly to the IRB all unanticipated problems and serious adverse events involving risk to human subjects (in accordance with required reporting timelines by the IRB (iv) Will accept responsibility to maintain original data and consent forms and submit them for review if requested.	descriptive						
847	name_of_principal_investig	Name of Principal Investigator	text						
848	signature_of_principal_inv	Signature of Principal Investigator	file (signature)						
849	date1	Date	text (date_dmy)						
850	name_of_line_manager	Name of Line Manager	text						
851	signature_of_line_manager	Signature of Line Manager	file (signature)						
852	date2	Date	text (date_dmy)						
853	irb413_research_proposal_template_complete	Section Header: <i>Form Status</i> Complete?	<div>dropdown</div> <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
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