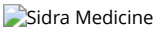

Sidra Medicine
Research - Biomedical Informatics

IRB PID 21

Project Home | Codebook

Codebook

Data Dictionary Codebook

05-15-2025 06:27

Collapse all instruments

#	Variable / Field Name	Field Label *Field Note*	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)
Instrument: **IRB** (irb)			Collapse
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) 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;
6	add_notification_email_irb	Select Additional Email to receive Notifications	sql (autocomplete) 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;
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] *a number only, no text*	text (number)
26	is_this_protocol_using_sam	Is this protocol using samples from patients requited 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] *a number only, no text*	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: *a number only, no text*	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 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 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
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	sql (autocomplete) 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'; Field Annotation: @HIDDEN
42	pmohandlingirb	Section Header: *Relation to Project Overview* PMO handling of this IRB	radio 1, This IRB is part of one or more projects and will be linked 2, This IRB does not need project registration Field Annotation: @HIDDEN
43	whynoproject Show the field ONLY if: [pmohandlingirb] = '2'	Explain why it does not need project registration	dropdown 1, Social Science / Administration e.g. for Advanced Degree of Staff Member 2, Project to improve quality of standard procedures 10, Other
44	furtherwhynorproject Show the field ONLY if: [whynoproject] = '10'	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	Section Header: *Documents Please use "IRB Regulatory Binder Documents" Column for more Document upload. (here limited to: Approval letter, Proposal, IRBNet Application)* IRB Decision Letter *IRB Decision Letter*	file, Required
49	irb_reliance_form	IRB Reliance Form	file
50	initial_approval_letter	Initial approval letter *First ever approval letter*	file Field Annotation: @HIDDEN
51	proposal_upload	Research Proposal *Proposal*	file
52	protocol_uplod	Protocol *Protocol*	file Field Annotation: @HIDDEN @READONLY
53	mophletter Show the field ONLY if: [interventional_yn] = '1'	Please upload approval letter from MoPH for your Interventional Clinical Trial.	file Field Annotation: @HIDDEN @READONLY
54	irb_amendment	IRB amendment *Latest amendment letter (i.e. new name on board)*	file Field Annotation: @HIDDEN
55	irb_application	IRB Application *IRB application initial, Related to Binder Study Concept Documents*	file
56	irb_renewal	IRB renewal Application *Renewal application for IRB*	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) *Related to Binder Category 12*	file Field Annotation: @HIDDEN @READONLY
59	screenform	Subject Screening / Enrollment Log Form *Related to Binder Category 13*	file Field Annotation: @HIDDEN
60	closure_report	Study Closure Report (Study closure and Analysis) *Closure report*	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): *Related to Binder Category 15*	file Field Annotation: @HIDDEN @READONLY
62	safetydoc	Study Activation and Conduct Documents IIG) Safety Documents, if applicable *Related to Binder Category 18*	file Field Annotation: @HIDDEN @READONLY

63	saereportform	SAE / AE Reporting Form *Related to Binder Category 19*	file Field Annotation: @HIDDEN @READONLY
64	other	Other *Space for other relevant documents*	file Field Annotation: @HIDDEN @READONLY
65	update_pmo1	PMO Last update	text (date_dmy)
66	irb_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Progress Subject Enrollment** (progress_subject_enrollment)			Collapse
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? *a number only, no text*	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: *Form Status* Complete?	dropdown 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: *Form Status* 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) 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
92	role_as_irbnet	Please select the role of the research team member as per IRBNet entry:	dropdown (autocomplete), Required 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

<table>
<tr><td>93</td><td>other_role_irbnet

Show the field ONLY if:
[role_as_irbnet] = '10'</td><td>Please define Other, if selected above.</td><td>text</td></tr>
<tr><td>94</td><td>personirb2</td><td>Please select the responsibilities of the person as per IRB Application.
LPI by default all granted</td><td>checkbox<table><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></td></tr>
<tr><td>95</td><td>other_role_irb

Show the field ONLY if:
[personirb2(8)] = '1'</td><td>Please define Other:</td><td>text</td></tr>
<tr><td>96</td><td>statutuspersonirb</td><td>Please select the status of the person's participation.</td><td>dropdown (autocomplete)<table><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</td></tr>
<tr><td>97</td><td>otherstatusp

Show the field ONLY if:
[statutuspersonirb] = '4'</td><td>Please define other:</td><td>text
Field Annotation: @HIDDEN</td></tr>
<tr><td>98</td><td>personirb3

Show the field ONLY if:
[statutuspersonirb] = '4'</td><td>Please define others if ticked above.</td><td>text
Field Annotation: @HIDDEN</td></tr>
<tr><td>99</td><td>connect_l500_irb</td><td>Please select the relevant Research related Conflict of Interest Declaration - L-500A Form.</td><td>sql (autocomplete)
SELECT CONCAT(irb, '(', email, ')(', CASE WHEN sdr IS NULL THEN 'NA' ELSE sdr END, ')') AS l500 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</td></tr>
</table>

100	addedtoexempt Show the field ONLY if: [protocol_type] = '1'	Section Header: 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. If you add a person under these circumstances, then please click "Yes". Otherwise keep blank or click Not Applicable.	radio 1 Yes 2 Not Applicable
101	how_submit_prime_access	Section Header: 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.	radio 1 Click here to see more Information 2 Don't need more info
102	info_prime_res_enrol Show the field ONLY if: [how_submit_prime_access] = '1'	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 "	descriptive
103	info_prime_clinical_data Show the field ONLY if: [how_submit_prime_access] = '1'	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"	descriptive
104	info_prime_sample Show the field ONLY if: [how_submit_prime_access] = '1'	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 "	descriptive
105	infor_prime_project_info Show the field ONLY if: [how_submit_prime_access] = '1'	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"	descriptive
106	redcap_regstry	Section Header: Access for a REDCap based tool to collect patient data	radio 1 Yes 2 No
107	pmo_approval Show the field ONLY if: [add_prime_approval] = '1'	Section Header: *Below use for PMO ONLY* Approved for PRIME / (REDCap Patient data)	radio 1 Yes 2 No
108	prime_ok_expiry Show the field ONLY if: [pmo_approval] = '1'	Approval will expire on:current IRB approval until: [expiry_date_2]	text (date_dmy) Field Annotation: @DEFAULT=[expiry_date_2]
109	note_prime_yes Show the field ONLY if: [pmo_approval] = '1'	Approved by PMO to be used in PRIME	descriptive

110	please_select_the_responsi Show the field ONLY if: [pmo_approval] = '1'	Please select the responsibilities of the person as per PRIME Access Request (tick all that apply)	checkbox 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	access_request_to_prime Show the field ONLY if: [pmo_approval] = '1' or [pmo_approval] = '2'	Access Request to PRIME	descriptive
112	request_prime_access 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')	Research Enrollment	descriptive
113	research_enrollment_val	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	request_prime_access_2 Show the field ONLY if: [pmo_approval] = '1' and ([personirb2(10)] = '1' or [personirb2(9)] = '1' or [personirb2(7)] = '1' or [personirb2(6)] = '1')	Clinical Data Manager	descriptive
115	clinical_data_manager_valu	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	request_prime_access_3 Show the field ONLY if: [pmo_approval] = '1' and ([personirb2(9)] = '1' or [personirb2(10)] = '1')	Sample (Lab) Inventory	descriptive
117	sample_lab_inventory_val	Sample (Lab) Inventory value	calc Calculation: if(([pmo_approval] = '1' and ([personirb2(9)] = '1' or [personirb2(10)] = '1')) =1, 1, 0)
118	request_prime_access_4 Show the field ONLY if: [pmo_approval] = '1' and ([personirb2(10)] = '1')	Project Info	descriptive
119	project_info_value	Project Info value	calc Calculation: if(([pmo_approval] = '1' and ([personirb2(10)] = '1')) =1, 1, 0)
120	request_prime_access_5 Show the field ONLY if: [pmo_approval] = '2'	No Access to PRIME needed	descriptive
121	comments_person	Section Header: Space for comments	text Field Annotation: @CHARLIMIT=250
122	update_pmo2	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: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: **Dependent IRB's** (dependent_irbs)			Collapse
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) 1, Exempt 2, Expedited 3, Full Board 10, Other
128	renewal_collirb	Does it need a renewal?	yesno 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: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: **Consent Checklist** (consent_checklist)			Collapse
135	template	Section Header: *Checklist for all Mandatory parts as per IRB Template* The content was copied from a template for:	radio 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 1, Yes 0, No
139	background	Does the form include Background & Purpose?	yesno 1, Yes 0, No
140	number_of_subjects_q	Does the form include number of subjects?	yesno 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: *Procedure Details* 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	checkbox 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
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 *click what applies*	checkbox 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
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 *click what applies*	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
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 *click what applies*	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
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 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 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
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 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 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_outcomes] = '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 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 [research_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: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Consent Form MetaData** (consent_form_metadata)			Collapse
233	consent_options	CONSENT OPTIONS	descriptive
234	consent_form_waiver	Consent Form Waiver	yesno 1 Yes 0 No
235	off_protocol_use	Off-Protocol sample use	dropdown (autocomplete) 1 On 2 Off 3 Option 4 Not Applicable
236	basic_research	Basic research	dropdown (autocomplete) 1 On 2 Off 3 Option 4 Not Applicable
237	followup_contact	Follow-up contact for other studies	dropdown (autocomplete) 1 On 2 Off 3 Option 4 Not Applicable
238	contact_for_similar_studie	Contact for similar studies	dropdown (autocomplete) 1 On 2 Off 3 Option 4 Not Applicable
239	cell_line_creation	Cell-line creation	dropdown (autocomplete) 1 On 2 Off 3 Option 4 Not Applicable
240	germ_line_genetics	Germ-line genetics	dropdown (autocomplete) 1 On 2 Off 3 Option 4 Not Applicable
241	store_future_use	Store and share sample for future use	dropdown (autocomplete) 1 On 2 Off 3 Option 4 Not Applicable
242	store_use_information	Store and share information for future use	dropdown (autocomplete) 1 On 2 Off 3 Option 4 Not Applicable

243	followup_visits_samples	Follow-up visits for giving samples	dropdown (autocomplete) 1 On 2 Off 3 Option 4 Not Applicable
244	incidental_findings	Incidental findings	dropdown (autocomplete) 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) 1 Yes 2 No 3 Optional
247	saliva_sampling_type	Saliva	dropdown (autocomplete) 1 Yes 2 No 3 Optional
248	stool_sampling_type	Stool	dropdown (autocomplete) 1 Yes 2 No 3 Optional
249	urine_sampling_type	Urine	dropdown (autocomplete) 1 Yes 2 No 3 Optional
250	left_over_tissue_samples_sampling_type	Left over tissue samples from pathology	dropdown (autocomplete) 1 Yes 2 No 3 Optional
251	left_over_biopsy_sampling_type	Left over Biopsy	dropdown (autocomplete) 1 Yes 2 No 3 Optional
252	skin_swab_sampling_type	Skin swab	dropdown (autocomplete) 1 Yes 2 No 3 Optional
253	buccal_swab_sampling_type	Buccal swab	dropdown (autocomplete) 1 Yes 2 No 3 Optional
254	placental_tissue_sampling_type	Placental tissue	dropdown (autocomplete) 1 Yes 2 No 3 Optional
255	amniotic_fluid_sampling_type	Amniotic fluid	dropdown (autocomplete) 1 Yes 2 No 3 Optional

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

268	donating_samples_saliva	Donating samples-Saliva	dropdown (autocomplete) 1, On 2, Off 3, Option 4, Not Applicable Field Annotation: @HIDDEN
269	donating_samples_csf	Donating samples-CSF	dropdown (autocomplete) 1, On 2, Off 3, Option 4, Not Applicable Field Annotation: @HIDDEN
270	left_over_material	Left over diagnostic material use	dropdown (autocomplete) 1, On 2, Off 3, Option 4, Not Applicable Field Annotation: @HIDDEN
271	donating_other_samples	Donating other samples	dropdown (autocomplete) 1, On 2, Off 3, Option 4, Not Applicable Field Annotation: @HIDDEN
272	protocols_allows_for_recru	Protocols allows for recruitment of anonymized patients (These are patient have been de-identified permanently)	dropdown (autocomplete) 1, YES 2, NO Field Annotation: @HIDDEN
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 1, Yes 0, No Field Annotation: @HIDDEN
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 1, Yes 0, No Field Annotation: @HIDDEN
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 1, Leftover samples only 2, Leftover and additional research samples, as specified above Field Annotation: @HIDDEN
278	informed_about_incidental	Section Header: Informed about incidental clinical findings	dropdown (autocomplete) 1, On 2, Off 3, Option 4, Not Applicable

279	contact_you_for_future_res	Contact you for future research studies	dropdown (autocomplete) 1 On 2 Off 3 Option 4 Not Applicable
280	leftover_samples_only	Leftover samples only	dropdown (autocomplete) 1 On 2 Off 3 Option 4 Not Applicable
281	leftover_and_additional_re	Leftover and additional research samples	dropdown (autocomplete) 1 On 2 Off 3 Option 4 Not Applicable
282	consent_form_metadata_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Data Collection Form I - standard fields** (data_collection_form_i_standard_fields) Collapse			
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 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 1 Unique Patient Study number Field Annotation: @DEFAULT='1'
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 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 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 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 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 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 1, E-mail address
297	pii_qid Show the field ONLY if: [standard_fields(2)] = '1'	3.7. Qatar ID number	radio 1, Qatar ID number
298	pii_passport Show the field ONLY if: [standard_fields(2)] = '1'	3.8. Passport Number	radio 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 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 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 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 1, Car number plate
305	pii_ip Show the field ONLY if: [standard_fields(2)] = '1'	3.13. Internet Protocol (IP) address numbers	radio 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 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 1, Biometric indentifier

308	pii_photo Show the field ONLY if: [standard_fields(2)] = '1'	3.16. Full face photographic images	radio 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 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 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 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 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 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: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Data Collection Form II - custom fields** (data_collection_form_ii_custom_fields) Collapse			
319	dcf_field_name_custom	Data Collection field name	text

320	dcf_type_of_field	Please select nature of field	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: *Form Status* 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	radio 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	select_study_concept Show the field ONLY if: [binder_chapter] = '1'	Study Concept	radio 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	select_planning_creation Show the field ONLY if: [binder_chapter] = '2'	STUDY PLANNING & CREATION	radio 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
329	select_iia Show the field ONLY if: [select_planning_creation] = '1'	IIA Institutional Review Board (IRB) Approvals and correspondence (2.1)	radio 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)

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

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

348	upload_binder_doc Show the field ONLY if: [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_iia] = '1' or [select_iia] = '2' or [select_iia] = '3' or [select_iia] = '4' or [select_iia] = '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_activation] = '1' or [select_activation] = '6' or [select_activation] = '7' 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'	Upload the Document	file
349	comment_binder_doc	Comment	text
350	assign_later	Upload assign later	radio 1, click
351	documents_related_to_your_irb_complete	Section Header: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: **PHI - PRIME** (phi_prime)			Collapse
352	phi_prime	Please click which PHI data are collected for your study:	checkbox 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
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: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Prime Access Request Form** (prime_access_request_form)			Collapse
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: *Submission* 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: *PMO use only below* StatusPMO has checked all entries and has ...	radio 1 Approved 2 Open Questions
364	prime_access_request_form_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **PMO Internal** (pmo_internal)			Collapse
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 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: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **PMO Inspection Checklist** (pmo_inspection_checklist)			Collapse
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: *Data on Shared Drive* Folder Created	checkbox 1 shareddrive1___1 Not Checked 2 shareddrive1___2 Checked - OK 3 shareddrive1___3 Checked - Attention Needed
381	shareddrive2	Folder with IRB created/exists	checkbox 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 1 shareddrive3___1 Not Checked 2 shareddrive3___2 Checked - OK 3 shareddrive3___3 Checked - Attention Needed
383	attention_s_drive Show the field ONLY if: [shareddrive2(3)] = '1' or [shareddrive3(3)] = '1' or [shareddrive1(3)] = '1'	What needs to be done?	notes
384	people_cross_chk	Section Header: *IRB Application Check* Cross check info application and on people	radio (Matrix) 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) 1 Not Checked (this time) 2 Checked - OK 3 Checked - Attention Needed

386	l500_connect	Ensure L-500A is connected	radio (Matrix) 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) 1 Not Checked (this time) 2 Checked - OK 3 Checked - Attention Needed
388	sdr_no_chk	SDR mentioned and correct	radio (Matrix) 1 Not Checked (this time) 2 Checked - OK 3 Checked - Attention Needed
389	prime_approvel	Add the PRIME approval	radio (Matrix) 1 Not Checked (this time) 2 Checked - OK 3 Checked - Attention Needed
390	upload_application	Upload Application in first instrument	radio (Matrix) 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 [l500_connect] = '3' or [number_patients] = '3' or [sdr_no_chk] = '3' or [prime_approvel] = '3' or [upload_application] = '3'	IRB Application needs Attention	notes
392	expiry_dt	Section Header: *Check Approval Letter* Check correct expiry date	radio (Matrix) 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) 1 Not Checked (this time) 2 Checked - OK 3 Checked - Attention needed
394	sample_size	Check approved Sample size	radio (Matrix) 1 Not Checked (this time) 2 Checked - OK 3 Checked - Attention needed
395	upload_approval	Upload Application in first instrument	radio (Matrix) 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: *Protocol / Proposal Check* Check people on protocol reflected on application	radio (Matrix) 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)	radio (Matrix) 1 Not Checked (this time) 2 Checked - OK 3 Checked - Attention Needed
399	retro_chk	If retrospective check if that is true	radio (Matrix) 1 Not Checked (this time) 2 Checked - OK 3 Checked - Attention Needed
400	upload_proposal	Upload Application in first instrument	radio (Matrix) 1 Not Checked (this time) 2 Checked - OK 3 Checked - Attention Needed
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: *Check 2 times a year* Consent Form Content digitilized	radio (Matrix) 1 Not Checked (this time) 2 Checked - OK 3 Checked - Attention Needed 4 Not Applicable
403	consent_meta	Create consent Meta Data	radio (Matrix) 1 Not Checked (this time) 2 Checked - OK 3 Checked - Attention Needed 4 Not Applicable
404	cros_chk_phi	Cross check PHI Prime	radio (Matrix) 1 Not Checked (this time) 2 Checked - OK 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: *Data collection Form* Cross Check Instrument PHI Prime	radio (Matrix) 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	radio (Matrix) 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: *IRBNet Data Import* Base data Report (imported, less than 3 months old)	radio (Matrix) 1 Not checked (this time) 2 Checked - OK 3 Checked - needs Attention

410	active_protocols	Active Protocols Report (imported, less than 3 months old)	radio (Matrix) 1 Not checked (this time) 2 Checked - OK 3 Checked - needs Attention
411	irb_ppl_import	Peopel on IRB Report (imported, less than 3 months old)	radio (Matrix) 1 Not checked (this time) 2 Checked - OK 3 Checked - needs Attention
412	coolaboration_report	Collaboration Report (imported, less than 3 months old)	radio (Matrix) 1 Not checked (this time) 2 Checked - OK 3 Checked - needs Attention
413	collaboration_contract	Check if Collaboration has Contract already	radio (Matrix) 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_data1] = '3'	IRBNet Import Attention needed:	notes
415	inspection_comment	Comment	notes
416	pmo_inspection_checklist_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **PMO Internal Documents** (pmo_internal_documents) Collapse			
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: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Cerner Registered Enrollment Forms** (cerner_registered_enrollment_forms) Collapse			

421	month_year	Month / Year	dropdown (autocomplete) 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
422	no_new_enrollment	Number of Enrollment Forms	text
423	cerner_registered_enrollment_forms_complete	Section Header: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: **CTO Monitoring Documents** (cto_monitoring_documents)			Collapse
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: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **CTO MOPH Approval** (cto_moph_approval)			Collapse
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: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **General Information Clinical Trial** (general_information_clinical_trial)			Collapse
437	trial_info	Please add in this section more information about the Trial	descriptive
438	sponsor_trial	Section Header: *Sponsor* Please select the sponsor of the study	radio 1 Sidra PI 2 External Sponsor (Pharma) 3 External Sponsor (Academia) 4 External Sponsor (Hospital) 5 other
439	other_sponsor Show the field ONLY if: [sponsor_trial] = '5'	Other:	text
440	insurance_cto	Section Header: *Insurance* Is there any insurance need?	yesno 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: *Contracts* Is there any contract with external partners? *if yes, check project for the links*	yesno 1 Yes 0 No
446	trial_budget_q	Section Header: *Budget* Is there a trial specific budget?	yesno 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): *in QAR*	text (number)
449	amountperpatient Show the field ONLY if: [trial_budget_q] = '1'	Amount per patient (in QAR) *in QAR*	text (number)

450	general_information_clinical_trial_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **CTO Monitoring Plan** (cto_monitoring_plan)			Collapse
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) 1 weekly 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: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **CTO Monitoring Visit Log** (cto_monitoring_visit_log)			Collapse
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) 1 add person dropdown
461	comment_monivisit	Comment	text
462	cto_monitoring_visit_log_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **CTO Monitoring Report Part 1** (cto_monitoring_report_part_1)			Collapse
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 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? *for several issues, chose clossest date*	text (date_dmy)
468	comment_report	Comment	text
469	cto_monitoring_report_part_1_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **CTO Monitoring Report Part 2 Issue register** (cto_monitoring_report_part_2_issue_register)			Collapse

470	cto_monitoring_report_part_2_issue_register_complete	Section Header: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: **CTO Issue log** (cto_issue_log)			Collapse
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 1, New Issue 2, Follow-up Issue
474	cto_class_issue	Classification	radio 1, Minor 2, Major 3, Critical Field Annotation: @HIDDEN
475	cto_origin_issue	Origin of issue	radio 1, Protocol deviation 2, found during inspection 3, new policy Field Annotation: @HIDDEN
476	standard_issues	Category Issues	checkbox 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: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: **CTO Delegation of Authority Log** (cto_delegation_of_authority_log)			Collapse
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: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: **IRBNet Import 16709Base** (irbnet_import_16709base)			Collapse
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	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_research	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_participants	Overall Number of Participants	text
542	number_participants_sidra_only	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_sampel	Specify Research Procedures_Collection of blood sampl	text
557	procedures_pros_coll1	Specify Research Procedures_Prospective collection of	text
558	procedures_prosp_coll2	Specify Research Procedures_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: *Form Status* Complete?	dropdown 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: *Form Status* Complete?	dropdown 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 1, Removed
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	resposnibility_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: *Form Status* 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: *Form Status* 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 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: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: **IRBNet Import DrugsApplied** (irbnet_import_drugsapplied) Collapse			
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: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: **IRBNet Import MedicalDevices** (irbnet_import_medicaldevices) Collapse			
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: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: **IRB-408-A Modification Form - For Research Personnel Change** (irb408a_modification_form_for_research_personnel_c) Collapse			
676	modification	Modification Date:	text (date_dmy), Required

677	info	1. Information To change research personnel whether to add or to remove members from your study, submit the following: 1. Modification Form IRB-408-A. 2. Modified Main Study Application • Update section II of your current approved version of the main study application • This Modification should take place through IRBNET	descriptive
678	study_status	2. Current Study Status Check one option:	radio, Required 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	3. Personnel Change Check what is applicable:	checkbox, Required 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?	dropdown, Required 1 Yes 2 No
681	revised_doc Show the field ONLY if: [removing_personnel] = '1'	If yes, list the revised documents: Type/write document(s) name(s):	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?	dropdown, Required 1 Yes 2 No
684	yes_revised Show the field ONLY if: [revision_to_study_doc] = '1'	If yes, list the revised documents: Type/write document(s) name(s):	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	4. Principal Investigator (PI) Attestation By submitting this form, the PI attests to comply with Sidra Medicine policies and procedures.	descriptive
687	irb408a_modification_form_for_research_personnel_c_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **IRB-408-B- Modification Form - Research Study** (irb408b_modification_form_research_study) Collapse			
688	modification_date	Modification Date:	text (date_dmy), Required
689	info2	1. Information Attach the following: 1. Modification Form IRB-408-B. 2. Modified Main Study Application • Update the appropriate section of your current approved version of the main study application (if applicable) • This Modification should take place through IRBNET	descriptive

690	modified_materials	2. Modified Materials	checkbox, Required 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
691	ifother Show the field ONLY if: [modified_materials(20)] = '1'	If other, please specify.	text
692	study_status2	3. Current Study Status	radio 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
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 1, Not applicable - no subjects enrolled 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: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: **IRB-412-Closure Report Form** (irb412_closure_report_form)			Collapse
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	lpi	Principal Investigator: [lpi_irb]	text Field Annotation: @READONLY
709	submission_date	Submission Date:	text (date_dmy), Required
710	i_reason_for_closure	Section Header: *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. REASON FOR CLOSURE Check one option.	radio, Required 1, The study is complete 2, The study is cancelled (No work has been initiated, no data or samples have been collected) 3, Others

<table>
<tr><td>711</td><td>confirm_completion_of_all

Show the field ONLY if:
[i_reason_for_closure] = '1'</td><td>Confirm completion of all the below. All boxes must be checked for appropriate closure:</td><td>checkbox<table>
<tr><td>1</td><td>confirm_completion_of_all___1</td><td>All Subjects' recruitment & enrollment is complete. All research-related procedures, interactions or interventions including long term follow up is complete.</td></tr>
<tr><td>2</td><td>confirm_completion_of_all___2</td><td>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).</td></tr>
<tr><td>3</td><td>confirm_completion_of_all___3</td><td>Analyses of private identifiable information (data, specimens) are complete.</td></tr>
<tr><td>4</td><td>confirm_completion_of_all___4</td><td>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.)</td></tr>
</table></td></tr>
<tr><td>712</td><td>reason_cancel

Show the field ONLY if:
[i_reason_for_closure] = '2'</td><td>State the reason(s) of cancellation:</td><td>text, Required</td></tr>
<tr><td>713</td><td>explain

Show the field ONLY if:
[i_reason_for_closure] = '3'</td><td>Explain:</td><td>text, Required</td></tr>
<tr><td>714</td><td>ii_c_for_studies_funded_by</td><td>II. C. FOR STUDIES FUNDED BY EXTERNAL ENTITIES (example: Industry, Foundation ...etc.)</td><td>descriptive</td></tr>
</table>

715	funding_entity	Has the funding entity completed the closeout visit?	radio, Required 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 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 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_statu	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_cont	Date of last visit or contact with subject for research purposes	text (date_dmy)
725	study_activities_are_suspe	Study activities are SUSPENDED, provide date of suspension:	text (date_dmy)
726	date_subject_enrollment_wa	Date Subject Enrollment was opened.	text (date_dmy)
727	date_subject_closed	Date Subject Enrollment was closed.	text (date_dmy)
728	withdrawals	Were there any Subjects' withdrawals?	yesno, Required 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 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_d 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	explain_not Show the field ONLY if: [scientific_publications_re] = '2'	Explain:	text
798	data_safety_monitoring_rep	Data Safety monitoring Report	dropdown 1 Available 2 Not available 3 Not applicable
799	copy_attached2 Show the field ONLY if: [data_safety_monitoring_rep] = '1'	Copy attached	file
800	explain_not2 Show the field ONLY if: [data_safety_monitoring_rep] = '2'	Explain:	text
801	frequency_of_dsmb_dmc_revi Show the field ONLY if: [data_safety_monitoring_rep] = '2'	Frequency of DSMB/DMC Review:	text
802	expected_date_of_next_repo Show the field ONLY if: [data_safety_monitoring_rep] = '2'	Expected Date of next report:	text (date_dmy)
803	is_there_any_change_to_the Show the field ONLY if: [data_safety_monitoring_rep] = '2'	Is there any change to the Monitoring plan:	text
804	study_follow_up	Study Monitoring Report or Follow up Letter / Audit Report	dropdown 1 Available 2 Not available 3 Not applicable
805	copy_attached3 Show the field ONLY if: [study_follow_up] = '1'	Copy attached	file
806	explain3 Show the field ONLY if: [study_follow_up] = '2'	Explain	text
807	interim_findings	Interim findings	dropdown 1 Available 2 Not available 3 Not applicable
808	copy_attached4 Show the field ONLY if: [interim_findings] = '1'	Copy attached.	file
809	explain4 Show the field ONLY if: [interim_findings] = '2'	Explain	text
810	multi_center_trial_reports	Multi- center trial reports	dropdown 1 Available 2 Not available 3 Not applicable
811	copy_attached5 Show the field ONLY if: [multi_center_trial_reports] = '1'	Copy attached	file
812	explain5 Show the field ONLY if: [multi_center_trial_reports] = '2'	Explain	text

813	x_retention_of_study_recor	X. RETENTION OF STUDY RECORDS	descriptive
814	confirm_by_checking_the_bo	Confirm by checking the box that the PI will retain the records relating to research for at least 3 years after completion of the research and closure by the IRB* *Retention of records for a longer period might apply depending on the type of research and the applicable regulations (Like IND, IDE, abbreviated IDE or Funding/contract agreement)	radio, Required 1 Confirmed
815	specify_the_storage_locati	Specify the storage Location of all data/ research records (Hardcopies & Electronic)	text
816	indicate_the_retention_per	Indicate the retention period required by the contract or the grant:	text
817	xi_completion_of_report	XI. COMPLETION OF REPORT	descriptive
818	by_submitting_this_form_th	By Submitting this form, the Principal Investigator certifies that all information mentioned in this report is accurate and attests to comply with Sidra Medicine Policies & Procedures	descriptive
819	principal_investigator_nam	Principal Investigator Name:	text
820	date	Date:	text (date_dmy)
821	irb412_closure_report_form_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **IRB-413- Research Proposal Template** (irb413_research_proposal_template) Collapse			
822	research_proposal_title	Research Proposal Title:	text, Required
823	name_last_first_mi	Section Header: *Research Investigator:* Name (Last, First, MI):	text, Required
824	title_and_degrees	Title and Degrees:	text
825	department	Department:	text
826	phone_number_s	Phone Number(s):	text (number)
827	sidra_email	Sidra Email:	text (email)
828	name_last_first_mi2	Section Header: *Co- Research Investigator: (If any)* Name (Last, First, MI):	text
829	title_and_degrees2	Title and Degrees:	text
830	department2	Department:	text
831	phone_number_s2	Phone Number(s):	text (number)
832	sidra_email2	Sidra Email:	text (email)
833	summary_limit_to_1_page	Summary: (Limit to 1 page)	text
834	introduction_include_a_cri	Introduction: (Include a critical review of current knowledge or literature, including published and unpublished work in the area. Any hops in evidence should be identified theoretical clinical application of project outcome explored)	text
835	research_objective_state_a	Research Objective: (State aims and objectives concisely defined, following on from hypothesis)	text
836	research_methods_study_des	Research Methods: (Study Design and methods including the research questions, setting, participant(s), inclusion and exclusion, data analysis, retention strategies and withdrawal criteria)	text
837	data_collection_management	Data collection management and methods of assessment or measurement of data.	text
838	outcome_measures_and_end_p	Outcome measures and end points	text
839	provisions	Provisions for monitor Data to Ensure the Safety of Subjects (briefly describe any plan or committees responsible for reviewing and monitoring research conduct, data, quality, safety)	text

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 flaw 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: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete