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| IRB-412 - CLOSURE REPORT FORM | | | | | |
| Study Title: |  | | | | |
| IRB Number: |  | | | | |
| SDR Number: |  | | | | |
| Principal Investigator: |  | | | | |
| Submission Date: | (dd/mmm/yyyy) | | | | |
| **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. | | | | | |
| 1. **REASON FOR CLOSURE**   Check one option | | | | | |
| The study is complete  Confirm completion of all the below. All boxes must be checked for appropriate closure:   1. All Subjects’ recruitment & enrollment is complete. All research-related procedures, interactions or interventions including long term follow up is complete. 2. Obtaining private identifiable information *(data, specimens)* is complete. 3. 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. 4. Analyses of private identifiable information *(data, specimens)* are complete 5. 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) | | | | | |
| The study is cancelled (No work has been initiated, no data or samples have been collected)  State the reason(s) of cancellation: | | | | | |
| Others; Explain: | | | | | |
| 1. **C. FOR STUDIES FUNDED BY EXTERNAL ENTITIES (example: Industry, Foundation ...etc.)** | | | | | |
| Has the funding entity completed the closeout visit?  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.  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.  Clarification: | | | | | |
| Does a final report have to be submitted to the external entity?  Yes  No  Clarification: | | | | | |
| Has this final report submitted to the external entity?  Yes  No  If yes, please specify to whom: | | | | | |
| 1. **SUBJECTS ACCRUAL STATUS SINCE LAST CONTINUING REVIEW**   Respond to the below for subjects enrolled at Sidra only | | | | | |
| Number of enrolled Subjects   *(# of subjects who signed ICF. For research with waiver of IC, # of subjects who are included; or # of samples/records)* | | |  | | |
| Recruitment Finished: Date Last participant was consented | | | /       /  DD MMM YYYY | | |
| Date of last visit or contact with subject for research purposes | | | /       /  DD MMM YYYY | | |
| Study activities are SUSPENDED, provide date of suspension: | | | /       /  DD MMM YYYY | | |
| Date Subject Enrollment was opened | | | /       /  DD MMM YYYY | | |
| Date Subject Enrollment was closed | | | /       /  DD MMM YYYY | | |
| **Respond to the below for subjects enrolled at Sidra only** | | | | | |
| Were there any Subjects’ withdrawals? | | | Yes  No | | |
| Number of subjects who withdrew | | |  | | |
| Provide the reason (s) for withdrawal | | |  | | |
| Did you discontinue any Subject ’s participation?  *(PI /team stopped subject participation early before reaching the study endpoint)* | | | Yes  No | | |
| Number of discontinuations | | |  | | |
| Provide the reason (s) for discontinuing Subjects participation | | |  | | |
| **Please attach to this report a copy of last signed Informed Consent Form and/or signed Assent form (after hiding subject’s details)** | | | | | |
| 1. **SUMMARY OF THE RESEARCH FINDINGS**   Provide a summary of your research study findings. List all publications resulting from the study | | | | | |
|  | | | | | |
| 1. **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 | | | | | |
| Date of the event | | | Description of the event and its management | | |
| /       /  DD MMM YYYY | | |  | | |
| /       /  DD MMM YYYY | | |  | | |
| /       /  DD MMM YYYY | | |  | | |
| /       /  DD MMM YYYY | | |  | | |
| If no AEs took place since last continuing review, confirm by checking the below box:  Confirmed | | | | | |
| 1. **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 | | | | | |
| Date of the event | | Description of the event | | Correction action(s) | |
| /       /  DD MMM YYYY | |  | |  | |
| /       /  DD MMM YYYY | |  | |  | |
| /       /  DD MMM YYYY | |  | |  | |
| /       /  DD MMM YYYY | |  | |  | |
| If no Deviations took place since last continuing review, confirm by checking the below box:  Confirmed | | | | | |
| 1. **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 | | | | | |
| **Date of the event** | | **Description of the event and its management** | | **Were changes to the study materials needed? if yes, explain:**  **For serious/continuous noncompliance, describe the corrective actions:** | |
| /       /  DD MMM YYYY | |  | |  | |
| /       /  DD MMM YYYY | |  | |  | |
| /       /  DD MMM YYYY | |  | |  | |
| /       /  DD MMM YYYY | |  | |  | |
| /       /  DD MMM YYYY | |  | |  | |
| Were all the above unanticipated problems promptly reported to the IRB? | | Yes  No  If No, Justify below & fill in IRB-411 form | | | |
| If no UP took place since last continuing review, confirm by checking the below box:  Confirmed | | | | | |
| 1. **Update Since Last Continuing Review** The below is applicable to all study sites | | | | | |
| Did you receive any subject’s complaint about the study? | | | Yes  No  If yes, describe the subject complaint and how it was managed | | |
| Are you aware of any new risk or benefit related to the study not previously reported to the IRB? | | | Yes  No  If yes, Explain | | |
| Are you aware of any problems that require prompt reporting to the IRB not previously reported to the IRB? | | | Yes  No  If yes, Explain | | |
| Are you aware of any modifications to the study materials not previously reported to the IRB? | | | Yes  No  If yes, Explain | | |
| 1. **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 | | | | | |
| Scientific publications relevant to the risks or potential benefits of the study | Available  Copy attached | | Not available  Explain: | | Not applicable |
| Data Safety monitoring Report | Available  Copy attached | | Not available  Explain:                      Frequency of DSMB/DMC Review:  Expected Date of next report:        /       /  DD MMM YYYY Is there any change to the Monitoring plan: | | Not applicable |
| Study Monitoring Report or Follow up Letter / Audit Report | Available  Copy attached | | Not available  Explain: | | Not applicable |
| Interim findings | Available  Copy attached | | Not available  Explain: | | Not applicable |
| Multi- center trial reports | Available  Copy attached | | Not available  Explain: | | Not applicable |
| 1. **RETENTION OF STUDY RECORDS** | | | | | |
| 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\*  Confirmed  \**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)* | | | | | |
| Specify the storage Location of all data/ research records (*Hardcopies & Electronic*) | | | | | |
| Indicate the retention period required by the contract or the grant: | | | | | |
| 1. **COMPLETION OF REPORT** | | | | | |
| 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  Principal Investigator Name:                 Date:                (dd/mmm/yyyy) | | | | | |