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| Virginia Commonwealth University IRBRelying Site Closure report | | | |
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| **Closure Report Date:** | | | |
| **Relying Site Name:** | |  | |
| **relying Site Investigator Name:** | |  | |
| **Relying Site Investigator Contact Information:** | | Email Address:  Phone: | |
| **VCU IRB #:** | | | |
| **Title of Study:** |  | | |
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| **Instructions for submission:**  **The VCU Principal Investigator should work with the relying site investigator to Answer all questions completely and accurately.**  **When closing relying sites, but the study will remain open at vcu: Upload this form along with all supporting documentation (summaries, explanations and outside reports) in an amendment to the VCU IRB . On the Non-VCU Site details page, please also add the following statement (do not remove any information) to the closing site’s adequacy description: “A request to close this site from IRB oversight was submitted on XX/XX/XXXX date”.**  **When closing all sites, including vcu, via the closure process: upload this form along with all supporting documentation (summaries, explanations and outside reports) for each relying site that is open at the time of the closure request.** | | | |
| **To close the research at this relying site from VCU IRB oversight, verify all four of the following criteria are met for the relying site (all four boxes must be verified (checked) in order to close the study):**  Enrollment at the relying site is permanently closed.  All interactions/interventions with subjects and/or access to identifiable private information for the purpose of research data collection at/from the relying site is complete.  All use, study, and/or analysis of identifiable private information the relying site is completed.  The site is NOT the prime awardee of an ongoing direct federal award, where other sub award sites are remaining open. | | | |
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| 1. Identify why the study is being closed at this site (select one):   Study Completed: All study activities at this site have been concluded as described in the protocol and the above criteria in Question #1 are all met.  Premature Closure: All study activities at this site have permanently stopped earlier than anticipated by the protocol – *Attach an explanation of why the study is closing early. [Refer to Question #1]*  Study Withdrawn: All study activities at this site have stopped prior to enrollment of the first participant – *Attach an explanation of why the study is stopping. [Refer to Question #1]* | | | |
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| 1. At the relying site:    1. How many total participants have been enrolled to date?    2. How many participants have been enrolled since the date of the last IRB review (initial or continuing)? | | | *(enter number)*  *(enter number)* |
| The number of enrolled participants should include all individuals who:   * Provided consent (regardless of whether they completed any study activities) * Have contributed any data or specimens while participating in a research activity (interaction or intervention, including screening activities) * Have been represented in the secondary data/specimens (identifiable or not) obtained for the study | | | |

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| 1. Do the participants enrolled at this site represent the subject population described in the currently approved IRB application? | | Yes | | No |
| *If NO, either (a) attach an explanation that includes steps that you plan to take to ensure that the original population is represented including a timeframe for achieving this representation [Refer to Question #3],  OR (b) submit an amendment to the protocol to change the subject population.* | | | | |
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| 1. If the relying site uses an informed consent document(s), has the most recently approved version(s) been used throughout the past approval period? | N/A | Yes | | No |
| *If NO, attach an explanation of why the approved document(s) were not used. [Refer to Question #4]* | | | | |
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| 1. If the relying site includes children, were the enrolled children re-consented upon reaching the age of majority?   Yes  N/A - Site has not enrolled any children yet or no enrolled children at this site have reached age of majority to date  N/A – Study does not involve children or the site does not include children  No - The IRB approved a waiver of consent for the continued participation of children who reach age of majority  No - Other Reason *– Attach an explanation [Refer to Question #5]* | | | | |
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| 1. Since the last IRB review (initial or continuing), have any participants from this site withdrawn from the research? | | | Yes | No |
| *If YES, attach a summary of the numbers of withdrawals and their reasons. [Refer to Question #6]* | | | | |
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| 1. Since the last IRB review (initial or continuing), have any participants or others from this site complained about the research? | | | Yes | No |
| *If YES, attach a summary of the number and nature of the complaints. [Refer to Question #7]* | | | | |
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| 1. In the opinion of the relying site investigator, have there been changes to the risk/benefit profile for this research that would necessitate changes to the consent form? | | | Yes | No |
| *If YES, attach a summary description of those changes. [Refer to Question #8]* | | | | |
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| 1. Since the last IRB review (initial or continuing), have there been any    1. unanticipated problems at the relying site involving risks to participants or others, or    2. adverse events or adverse outcomes experienced by participants from this site? | | Yes | | No |
| *If YES, attach a summary of the unanticipated problems, adverse events, or adverse outcomes. [Refer to Question #9] See VCU’s policy on reportable events:* [*https://research.vcu.edu/human\_research/irb\_wpp/VII-6.htm*](https://research.vcu.edu/human_research/irb_wpp/VII-6.htm)*.* | | | | |
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| 1. Since the last IRB review (initial or continuing), have there been any changes or modifications to the research at the relying site that have NOT been submitted to the VCU IRB in an amendment*?* | | | Yes | No |
| *If YES, attach a description of those changes and submit an amendment. [Refer to Question #10]* | | | | |

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| 1. If this project is FDA-regulated research\*: | not FDA Regulated | | |
| 1. Does the relying site investigator remain in good standing with the FDA?   *If NO, attach an explanation. [Refer to Question #11]*   1. Has the relying site been audited by the FDA for this project since the last IRB review (initial or continuing)?   *If YES, attach a copy of the FDA Audit Report.* | | Yes  Yes | No  No |
| ***\**** *FDA-regulated research includes:*  *a) any research involving a drug or biologic intended for human use (other than the use of an approved drug in the course of medical practice);*  *b) any research designed to test the safety and effectiveness of a device; OR*  *c) research involving ANY FDA regulated product where the intent is to submit data to the FDA in support of a research or marketing application. Regulated products include foods & dietary supplements, infant formulas, food & color additives, and electronic products.* | | | |
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| 1. Have there been any changes in the relying site’s situation or the available resources that would affect the ability to conduct the study (e.g. human or fiscal resources or adequacy of facilities)? | | Yes | No |
| *If YES, attach an explanation of these changes and a plan for managing the changes OR submit an amendment to change the relying site investigator. [Refer to Question #12]* | | | |
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| 1. Have there been any changes in the qualifications of the research personnel at the relying site (e.g., suspension of hospital privileges, change in medical license status, or increase in number of research studies conducted by the investigator)? | | Yes | No |
| *If YES, attach an explanation of these changes and a plan for managing the changes OR submit an amendment to change the relying site investigator. [Refer to Question #13]* | | | |
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| 1. Does the relying site investigator certify that all engaged research personnel (as identified in the IRB submission personnel list for this site) maintain current human subjects research training? | | Yes | No |
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| 1. Provide a summary of the progress of the study at the relying site since the last IRB review (initial or continuing). This summary should include but is not limited to: 2. What research activities have been worked on during the past approval period. 3. Whether the relying site experienced any obstacles or delays in the conduct of the study during the past approval period. *If so, give a full explanation of what was encountered and how it was (or will be) resolved.* 4. Discussion of the progress of participants through the study procedures (e.g. progress through a longitudinal intervention, enrollment rates in each group/arm, etc.). | | | |
| Summary: | | | |