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| **Instructions** | | | | | |
| * Use this document to request closure and provide a final report to the IRB when human subject research activities are complete. * Human subject research activities are complete if your study will no longer:   + Obtain any more information or biospecimens about a living person for research through an interaction or intervention with the individual, and use, study, or analyze the information or biospecimen.   + Obtain, use, study, analyze, or generate any more identifiable private information or identifiable biospecimens about a living person for research. * FOR STUDIES THAT INVOLVE EXTERNAL SITES RELYING ON MSU FOR IRB REVIEW:   + If this study involves external sites relying upon MSU for IRB review of this study, please answer the questions for ALL external sites relying on MSU for IRB review.   + The study cannot be closed until relying sites have also completed ALL human research activities. * FOR STUDIES THAT INVOLVE MSU AS THE PRIMARY AWARDEE FOR A MULTI-SITE STUDY:   + Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS or other Common Rule agencies for the non-exempt human subjects research (i.e. primary awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution, are considered engaged in non-exempt human research.   + All human research activities at collaborating sites as part of the award must be complete before the study can be closed. * CLICK™ IRB   + Include this template with a Continuing Review Submission (when closing the study).   + Upload the completed template to the Continuing Review / Study Closure Information SmartForm page, Question 5. * See HRPP Manual 4-3, Determination of Human Subject Research for definitions and 8-9, Closure, for more information. | | | | | |
| **Complete Questions 1 – 11.** | | | | | |
| 1 | Study title. | | | | |
| 2A | Will your study obtain any more information or biospecimens about a living person for research through an interaction or intervention with the individual? | | | | **No  Yes** |
| 2B | Will your study obtain any more identifiable private information or identifiable biospecimens about a living person for research?   * *Identifiable information includes both direct (e.g. data labeled with subject name) and indirect (e.g. coded data that are linked to direct identifiers and data that are identifiable because indirect identifiers can be combined to readily identify an individual subject) identifiable information.* | | | | **No  Yes** |
| 2C | Will your study obtain, use, study, analyze, or generate any more identifiable private information or identifiable biospecimens about a living person for research? | | | | **No  Yes** |
|  | If the answer to 2A, 2B, or 2C is YES, the study still involves human subject research and the study cannot be closed. Please contact the IRB with any questions. | | | | |
| 3 | Does this study involve external sites that are relying on MSU for IRB review? | | | | **No  Yes** |
| If you answered YES, complete 3A and 3B. | | | | |
| 3A | Please describe the status of the study at the external site(s). | | | | |
| 3B | Select the appropriate option:  No human subject research activities are occurring for this study at the external site(s) that rely on MSU for IRB review. By checking the box, please confirm that no human subject research activities are occurring for this study at the external site(s) that rely on MSU for IRB review.  Confirmed  Human subject research activities are still ongoing – the study cannot be closed, please contact the IRB with any questions. | | | | |
| 4 | Why is this study being closed? | | | | |
| 5 | Can the identity of any subjects in your data be readily ascertained by the investigator or associated with the information or biospecimens (e.g. code to identifiers), either directly or indirectly? | | | **No**  **Yes** | |
| If you answered NO, please explain. | | |  | |
|  | If you answered YES, please complete 5A. | | |  | |
| 5A | If you would like to maintain information or biospecimens that allows the identity of subjects to be readily ascertained please explain why you would like to maintain identifiable data.   * *In general, identifiers should be removed once analyses of the identifiable data are complete, unless such information is essential or must be maintained as required by law or other requirements (e.g. FDA, funding agency, contract).* * *Please note that signed informed consent forms cannot be de-identified or redacted.* * *If the study data would allow individual subjects to be readily ascertained, any analyses of these data is research with human subjects. In order to analyze these data for research you must maintain IRB approval for the study or submit a new IRB application at MSU.* | | | | |
| 6 | By checking the box, please confirm that the Principal Investigator will retain the records relating to the research for at least three years after completion of the research.   * *Completion of the research occurs when all research and/or clinical investigations involving human subjects is complete and the project is closed by the IRB.* * *In addition, other regulations or requirements may apply and require retention of these records for a longer period of time or require retention of other specific records (e.g. clinical investigations conducted under an IND, IDE, or abbreviated IDE, contract or funding agreement requirements).* * *See HRPP Manual 4-7-A, Recordkeeping for Investigators for more information.*   Confirmed | | | | |
| 7 | How do you plan to ensure that the data and records relating to the research are securely stored and protected in a manner to maintain the confidentiality of the subjects and that is consistent with the IRB approved protocol and any relevant information in the consent document, when appropriate? | | | | |
| 8 | Please provide a brief summary of your study including relevant findings. | | | | |
| 9 | List all relevant publications resulting from this study. | | | | |
| 10 | Is this project registered with clinicaltrials.gov? | **No  Yes** | | | |
| If you answered YES, complete 10A. |  | | | |
| 10A | Is a MSU employee, MSU student, or agent of MSU listed as the Responsible Party with clinicaltrials.gov? | **No  Yes** | | | |
| If you answered NO, complete 10B. |  | | | |
| If you answered YES, complete 10C. |  | | | |
| 10B | The Responsible Party (e.g. Sponsor) is responsible to ensure all clinicaltrials.gov requirements with the ClinicalTrials.gov Protocol Registration and Results System are met.  By checking the box, please confirm that you will work with the Responsible Party as needed to ensure that all clinicaltrials.gov registration and results reporting requirements are met.  Confirmed | | | | |
| 10C | When a MSU employee, MSU student, or agent of MSU is the Responsible Party, they must complete all clinicaltrials.gov requirements with ClinicalTrials.gov Protocol Registration and Results System. *You may be contacted by the HRPP Compliance Office regarding the clinicaltrials.gov submission.*  Provide the date the Responsible Party will complete the submission to ClinicalTrials.gov to meet the requirements of clinicaltrials.gov registration and results reporting: | | | | |
| 11 | Was this project funded by an external entity (e.g. federal government, industry, foundation)? | **No  Yes** | | | |
| If you answered YES, complete 11A, 11B, 11C, and 11D. | | | | |
| 11A | Will the external entity conduct a closeout visit? | **No  Yes** | | | |
| If you answered YES, complete 11A1. | | | | |
| 11A1 | Has the closeout visit been conducted and all outstanding queries addressed? | **No  Yes** | | | |
| Please explain your answer to 11A1. | | | | |
| 11B | Does a final report need to be submitted to the external entity? | **No  Yes** | | | |
| If you answered YES, complete 11B1. | | | | |
| 11B1 | Has the final report been submitted? | **No  Yes** | | | |
| Please explain your answer to 11B1. | | | | |
| 11C | What is the data retention period required by the contract or grant? | | | | |
| 11D | Was MSU the primary awardee for a multi-site award? | | **No  Yes** | | |
| If you answered YES, complete 11D1. | | | | |
| 11D1 | Select the appropriate option:  No human subject research activities are occurring at the external site(s) as part of this study. By checking the box, please confirm that no human subject research activities are occurring at the external site(s) as part of this study.  Confirmed  Human subject research activities are still ongoing – depending on the status of the award, more information will be needed to determine if the study can be closed; please contact the IRB with any questions. | | | | |