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| **Section 400:** | **REVIEW OF RESEARCH** | | |
| **Standard Operating Procedure (SOP):** | **407 STUDY COMPLETION** | | |
| **This SOP pertains to:** | All Research submitted to the REBs | | |
| **Responsibility for executing this SOP:** | Director, Research Ethics, Research Ethics Staff, the Chairs of the U of S Research Ethics Boards | | |
| **Approval Authority** | The Vice-President Research | | |
| **Effective Date:** | July 1, 2012 | **Superseded documents dated:** | |

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| **1. PURPOSE:**<br>This SOP describes the procedures for closing a research project and the required notification of the REB. | **REFERENCES** |
| **2. POLICY:**<br>The completion of a study is a change in activity and must be reported to the REB. Although participants will no longer be "at risk" under the study, a final report/notice to the REB allows it to close its files as well as providing information that may be used by the REB in the evaluation and approval of related studies. | ICH-GCP Article 4.13<br>TCPS2 Article 6.14 |
| **3. SPECIFIC POLICIES**<br><br>**3.1.Determining When a Study can be Closed**<br><br>Studies may be considered completed and a Study Closure Form should be submitted as follows:<br><br>• Subject to US regulatory requirements, for studies that involve direct participant participation, no further participant contact is contemplated and all data collection procedures as per the approved protocol have been completed.<br>• Subject to US regulatory requirements, for studies that do not involve direct participant participation (i.e., secondary use of data), the acquisition of data is complete (i.e., no new cases are being added to the study dataset).<br>• For studies that analyze human tissue, no additional tissue samples are being withdrawn from or deposited to the tissue bank or being acquired from another research group.<br><br>Also:<br>• For an industry sponsored study there has been an official "close-out letter" from the sponsor.<br>• For a study monitored by the NCIC CTG to be considered complete the | |

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| Principal Investigator must have been notified by the NCIC CTG.<br><br>**US Federally Funded Research**<br>Studies that are funded or supported by the US Federal Government are considered open and subject to annual review requirements even where (i) the research is permanently closed to the enrollment of new participants; and (ii) all participants have completed all research-related interventions. Such studies may not be considered completed until all follow up of participants is final. If the remaining activities are limited to data analysis, there is no further analysis of individually identifiable information. | |
| **3.2. Content of Notification of Study Closure Report**<br><br>**3.2.1. Clinical Trials:**<br><br>The Study Closure Form should include:<br>• The Principal Investigator's affirmation that participant data collection is completed;<br>• Total number of research participants enrolled at the U of S (local) site;<br>• The number of serious and unexpected adverse events ;<br>• Date of Study Monitor's final visit;<br>• The final disposition/storage of all research-related study documents;<br>• The final disposition of any electronic data;<br>• A summary of results;<br>• Any other information relevant to the REB.<br><br>**3.2.2. Other Studies Enrolling Participants**<br><br>The Notification of Study Closure Form should include:<br>• The Principal Investigator's affirmation that participant data collection is completed;<br>• Total number of research participants enrolled at the U of S (local) site;<br>• The number of Serious and Unexpected Adverse Events;<br>• The final disposition/storage of all research-related study documents;<br>• The final disposition of any electronic data;<br>• A summary of results;<br>• Any other information relevant to the REB. | |
| **3.3. Study Closure**<br><br>Once the Notice of Closure has been reviewed by the REB, the REB will issue an Acknowledgement and the study will automatically be listed in the database as "Closed".<br>Normally, the study cannot be amended or reactivated. | |