Instructions for Completing the Final Closure Report Form

The Final Closure Report form should be completed when all human subject research activities have been completed, based upon the definition of when continuing review is no longer required for the version of the regulations being applied to this specific protocol (older regulations or revised regulations. Under the older regulations, the protocol may be closed when all data has been collected and data analysis of identifiable data is complete. Under the revised regulations, the protocol may be closed if the study is now limited to: Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.)

Indicate the date when the form was completed or revised.

Complete the PI and Faculty Sponsor information. This information should reflect what is currently approved on the protocol.

Section I: Provide the protocol number, title and current level of review for the research protocol, e.g. exempt, expedited, or full.

Section II: Indicate the reason for closing the protocol. Sometimes projects are not begun due to lack of time or funding or sometimes research is terminated early before completing the fully planned study. Indicate which reasons for closing the protocol applies to the research, based upon the version of the regulations currently being applied to this protocol.

Section III: Indicate the total number of subjects enrolled in the research. If you have multiple subject populations, such as adults and minors, students and teachers, provide the breakdown enrollment information as well.

If you have enrolled more than the approved number of subjects, indicate the reasons why this has occurred. Enrolling more subjects than you are approved for is a minor instance of non-compliance and the IRB will remind you that in the future you should submit an amendment increasing the number of approved subjects before you surpass the approved number.

Provide a summary of the study results. For example, what happened and what did you find out.

Indicate whether or not there were findings or results that would be considered new information to subjects. For example, maybe a new risk related to the research became known since the time the subjects provided consent. Then indicate if you plan on contacting the subjects who were enrolled in the study and your plan for doing so. Keep in mind that any emails, letter, or other

correspondence with subjects to inform them of the new information must be approved by the IRB before it is sent to the subjects.

Section IV: Indicate whether any subjects or their representative on their behalf, declined to be in the research. It is very common for people who are approached to be in a research project to say no. Therefore, the IRB anticipates that almost all studies will have subjects who declined to participate. For example, if you sent email invitations to two hundred people to complete a survey and you received one hundred responses, one hundred people decline to be in the study.

Section V: Indicate whether any subjects or their representative on their behalf withdrew from the research. It is very common for subjects to withdraw from research, particularly in a longitudinal study where there are many study time point over a course of a year or more. People who are nonresponsive or whom are unable to be reached for follow-up are considered as having withdrawn from the study.

Sometimes an investigator may make a choice to withdraw someone from a study. If that happens you should indicate that in this section. For example, there may have been changes in the subject's circumstances (e.g. health, moving or relocating) that now makes them ineligible to be in the study. In these cases an investigator may withdraw the subject administratively from the study.

Section VI: Indicate if you have received any subject complaints and indicate how you resolved that complaint. For example, subjects frequently call to indicate they did not receive payment, contact phone numbers no longer work, or that a procedure is too time-consuming. These are natural parts of conducting research. However, the IRB needs to know that subject complaints are being resolved in a timely manner.

Section VII: Indicate if you have had any unanticipated problems involving risks to subjects or others (UPIRSOs) or adverse events while you were conducting the research. When these events occur, they should be reported to the IRB in a timely manner. However, the person reviewing the final report may not be the person who reviewed the event when it was submitted to the office, so having a summary of all events that occurred and their resolution aids the IRB member(s) reviewing the final closure report to ensure that there are no outstanding issues that need to be addressed by the investigator before the study is closed.

Section VIII: Indicate whether or not any publications (including thesis or dissertations) resulted from the research.

Section IX: Indicate the current status or plan for the data collected for the research. Keep in mind that there is no federal requirement that the data be destroyed at any time. However, the IRB must ensure the risks to the subjects are minimized and that the direct and indirect identifiers (i.e. code linking an individual to the data) are destroyed as soon as feasibly possible. If the data is to be kept in an identifiable manner, the IRB would have to approve the rationale

for keeping the data identifiable and the protections in place for that data at the time of initial review.

Section X: The PI, and when applicable the Faculty Sponsor, should sign the form indicating the information in the Final Closure Report is complete and accurate. Since students frequently leave the university without fulfilling their obligation to complete the final report, a Faculty Sponsor may do so on behalf of the student if they have the information about the study available to them. If not, the Faculty Sponsor may ask that we close the study administratively by sending us an email stating that request.