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ST. MARY'S HOSPITAL CENTER ✧ RESEARCH REVIEW OFFICE
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FORM G - TERMINATION REPORT

PURPOSE: Use this form to report your study's completion.

INSTRUCTIONS:

1. Enter date on which the protocol was terminated. This means that neither subjects are being recruited or followed at SMHC.
2. Explain why your protocol has been terminated, either by checking off one of the boxes or by giving a brief explanation.
4. You are required to submit on a regular basis 1) all changes of the risk/benefit ratio possibly affecting subject (ongoing) participation in your study, and 2) all severe adverse events (SAEs), in the case of experimental intervention studies. If you have not reported either of these, then submit all such occurrences for the entire time during which your project was active.

Note: A serious adverse event is defined by the World Health Organization as:

A serious adverse event (experience) or reaction in any untoward medical occurrence that at any dose:

- * results in death,
- * is life-threatening

Note: The term "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

- * requires inpatient hospitalization or prolongation of existing hospitalization,
- * results in persistent or significant disability/incapacity, or
- * is a congenital anomaly/birth defect.

5. Should any publications on the study be available (accepted or published), submit them. Include any other dissemination materials as well. If you do plan to publish, forward all publications and/or other dissemination materials as soon as they are accepted.
6. Submit a final report containing a results summary or principal conclusion(s). This report need not be long and can summarize the main points. Include a plan for dissemination of results and/or conclusion(s). This final report is also required for projects lasting less than one year.
7. Ensure that the Principal Investigator (PI) signs the report. If the PI is not affiliated with St. Mary's Hospital Center, the Site Investigator must sign as well.



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DATE: -----/-----/-----
(yyyy/mm/dd)

FORM G - TERMINATION REPORT

Protocol #: _____ Principal Investigator: _____

SMHC Site Investigator (if applicable): _____

Full title of protocol: _____

Brief description of the protocol (attach additional sheets as needed): _____

1. Protocol termination date (yyyy/mm/dd): _____
2. Reason for protocol termination (check one):
 - reached accrual and/or data collection goals
 - no funding / insufficient funding received
 - unable to recruit enough subjects
 - protocol closed due to serious adverse event(s)
 - study discontinued by investigator (explain): _____
 - other (explain): _____

3. (a) Total number of subjects entered: _____
Total number of subjects entered at SMHC: _____
- (b) Total number of subjects completing protocol: _____
Total number of subjects completing at SMHC: _____

4. During the entire time period of your study, have you reported to the Research Ethics Committee 1) all new information affecting the risks and benefits of subject participation, and 2) all severe adverse events?
 Yes No [if no, submit reports for each] Not applicable [no human subjects]

5. Have any articles been published or other dissemination materials prepared using study results?
 No Yes [if yes, enclose copies]

6. Attach a final report containing a summary of study results and/or principal conclusions and state how you will disseminate them. Enclosed
 - (a) Was this report disseminated to the research participants? No Yes

I certify that as of _____(yyyy/mm/dd), subjects are no longer being recruited, studied or followed on the above protocol; therefore, this protocol is officially terminated at St. Mary's Hospital.

7. _____
Principal Investigator Date (yyyy/mm/dd)

St. Mary's Site Investigator (if PI not from SMH) Date (yyyy/mm/dd)