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ST. MARY'S HOSPITAL CENTER ✧ RESEARCH REVIEW OFFICE
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FORM F - INTERIM REPORT FORM

PURPOSE: Use this form to renew your study's annual approval or as requested by the Research Ethics Committee (REC). Submit it at least 30 days before your last approval period ends.

INSTRUCTIONS:

PART 1 – Project status (to be completed for all projects)

1. Write the current approval period as given to you 1) in your Full Institutional Approval letter or 2) at your last interim review.
3. (a) Indicate your project's current status:
 - Development: You are developing aspects of your study (e.g. finalizing sites, writing questionnaires, developing medication protocols, etc.).
 - Active: You are working on your protocol at SMHC (e.g. recruiting subjects, reviewing charts, conducting subject follow-up, etc.).
 - Closed to enrollment: The protocol is still active; however, you are no longer recruiting subjects.
 - Follow up: The protocol is still active and you are no longer recruiting subjects; however you are finishing follow-up visits, phone calls, etc. with the study participants.
 - Analysis: You are in the process of analyzing your data collected.
 - Interrupted: Your study is presently on hold (e.g. research assistant withdrew, revising study protocol, etc.)
 - Suspended: Your study has been suspended by an authority (funding agency, REB, institution, etc.)
 - Not started: You still have not started any work on your protocol.

(b) Give a brief explanation for each item selected above. You may attach additional sheets if needed.

PART 2 – New information and problems arising (to be completed for all projects)

4. Indicate if any new information (whether from your study or otherwise) that might affect 1) the risk/benefit ratio and/or a research participant's decision to participate or remain in your study, or 2) whether or not you will be able to complete the study that have not already been reported to the REC. If yes, then attach a report with a plan for how you inform your research participants.
5. Indicate if there have been any problems with the course of research (e.g. breach of study protocol, loss of institutional or funding-agency approval for the project, interruptions at other study sites, etc.) not already reported to the REC.
6. Indicate if there have been any undesirable reactions to non-experimental study procedures (e.g. severe bleeding after blood draw, panic attack in MRI scanner) at SMHC that have not already been reported to the REC. If yes, attach a report.
7. Inform us of any publications authored by your research team that have not already been reported to the REC. If there are, attach a copy.

PART 3 – Subject recruitment

(complete section only if project has human subjects and is still recruiting subjects)

8. Complete this question only if you are still recruiting subjects into your study. If so, indicate the date when you will stop all subject recruitment.
9. Append a clean, unmarked copy of the consent form you are presently using. It will have to be re-stamped by the REC.
10. Fill in the information as indicated in the table. You must complete a separate table for each study site under the auspices of the SMHC Principal Investigator or Site Investigator. Feel free to create your own table according to your study's need, so long as it contains all the requisite information.
11. If known, specify the reasons for why participants refused to consent to, were excluded or withdrew from your study. Note that good ethical practice states that you should not ask patients why they decided not to participate or withdraw if they are not forthcoming.
12. If you were asked to keep a subject log (see the letter of Full Institutional Approval), please attach a copy.

PART 4 – Adverse events (complete section only for experimental intervention studies)

13. Check whether or not there have been any SAEs related to the study medication, natural product or other intervention at SMHC or any of the other study only if you have not already reported them to the REC.
*Note: The World Health Organization (as endorsed by the MSSS) defines a serious adverse event (SAE) 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.*
13. Indicate the total number of SAE's which have occurred at all sites where your study is taking place. Include a denominator to better help the REC assess these SAE's. The denominator is the total number of subjects entered at all study sites worldwide.
14. Now indicate the number of those that have occurred at SMHC.
15. Attach reports of all these SAEs. Include in the report(s): 1) nature of SAE(s), 2) date on which SAE(s) occurred, and 3) any impact upon your study's protocol (i.e. if clinical equipoise has been upset, if there are new risks participants need to be aware of, change in study procedures, etc.).
16. Report if there are any other untoward medical occurrences related to any of your study's experimental interventions only at SMHC not already reported to REC. If yes, attach a report.

PART 5 – Signatures (complete for all projects)

17. Get the Principal Investigator to sign the report. If the PI is not affiliated with St. Mary's Hospital Center, then the site investigator must sign it as well.



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

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Protocol #: _____ Principal Investigator: _____

SMHC Site Investigator (if applicable): _____

Full title of protocol: _____

PART 1 – Project status (completed for all projects)

1. Current approval period (yyyy/mm/dd): _____ to _____

2. Anticipated project end date (yyyy/mm/dd): _____

3. (a) Indicate current project status (check those that apply):

- | | |
|---|--------------------------------------|
| <input type="checkbox"/> Development | <input type="checkbox"/> Analysis |
| <input type="checkbox"/> Active | <input type="checkbox"/> Interrupted |
| <input type="checkbox"/> Closed to enrollment | <input type="checkbox"/> Suspended |
| <input type="checkbox"/> Follow-up | <input type="checkbox"/> Not started |

(b) Provide a brief explanation below for each item selected (attach additional sheet if needed):

PART 2 – New information and problems arising (completed for all projects)

4. Has any new information become available 1) regarding the risks or benefits of subject participation (including continued participation) in the project or 2) affecting the feasibility of project completion that has not already been reported to the Research Ethics Committee (REC)?

No Yes [if yes, append details with a plan for how you will inform project participants]

5. Have any problems arisen with the course of research (including interruption at any study site) that have not already been reported to the REC?

No Yes [if yes, append details]

6. Have any undesirable reactions to non-experimental study procedures occurred at SMHC that have not already been reported to the REC?

No Yes [if yes, append details]

7. Have members of the research team published any articles or other dissemination materials have not already been forwarded to the REC?

No Yes [if yes, append a copy]

PART 3 – Subject recruitment (applies only to projects with human subjects)

8. If project is still open to subject recruitment, what is anticipated recruitment end date (yyyy/mm/dd)?
 _____ **Patient recruitment already closed**

9. Append a clean copy of your consent form. **Enclosed**

10. Fill in the following information regarding subject recruitment. If study is multi-centre, complete a separate table for each site under the jurisdiction of the SMHC-based PI or Site Investigator. You may report this information in a format more appropriate for your study.

	Total to date	Since last interim report
Number of subjects approached to participate in study*		
Out of those who were approached, number who refused to participate		
Out of those who were approached, number who were excluded from study		
Out of those who were approached, number who consented*		
Out of those who consented, number who completed study		
Out of those who consented, number who withdrew*		
Out of those who consented, number who are still under follow-up		
Other		

**Required for all experimental intervention studies*

11. Participants are not required to provide reasons for non-participation or withdrawal from a study. However, specify reasons for refusal, exclusion and withdrawal if known (attach separate sheet if needed): **Not known**

12. If you were asked to keep a subject log (see the letter of Full Institutional Approval, Appendix A), please attach a copy.
 Attached. **Not Applicable.**

PART 4 – Adverse events (applies only to experimental intervention studies)

13. Have any serious adverse events (SAEs) related to experimental devices/medications/procedures occurred at SMHC or any study sites that have not already been reported to the REC?
 No [if no, skip to question number #15] **Yes**

14. Total number of SAEs at all sites since initial approval/last interim review/immediate reporting?
 i. Denominator: _____ ii. Subjects enrolled worldwide: _____

15. Total number of SAEs at SMHC since initial approval/last interim review/immediate reporting?
 i. Denominator: _____ ii. Subjects enrolled worldwide: _____

16. Attach a report of all SAEs not already reported to REC including 1) nature of SAE(s), 2) date on which SAE(s) occurred, and 3) any impact upon study protocol.

17. Have any other untoward medical occurrences happened at SMHC that were not reported to the REC?
 No **Yes [if yes, append details]**

PART 5 – Signatures (complete for all projects)

18. Signatures:

 Principal Investigator Date (yyyy/mm/dd)

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