



Centre hospitalier affilié  
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Hospital Centre

**ST. MARY'S HOSPITAL CENTER ✧ RESEARCH REVIEW OFFICE**  
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## FORM E - IMMEDIATE REPORTING & AMENDMENT FORM

**PURPOSE:** Complete this form to report any new information, incidents and/or changes related to your study of which the Research Ethics Committee must be made aware and approve before next interim review.

### INSTRUCTIONS:

1. 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.). If yes, attach details.
2. 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. If yes, then attach a report with a plan for how you inform your research participants.
3. Complete this question only for experimental intervention studies (e.g. clinical trial).

*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.

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 sites. If yes, then append a report with specific details.

4. If you answered 'yes' to any of questions 2, 3 or 4, then indicate whether or not you have modified/amended study documents accordingly (including consent form). If no, then provide a justification for why not.
5. Check off any documents amended and write the date on which they were changed. Include a revised version of each with the changes highlighted.
6. 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)

**FORM E - IMMEDIATE REPORTING & AMENDMENT FORM**

Protocol #: \_\_\_\_\_ Principal Investigator: \_\_\_\_\_

SMHC Site Investigator (if applicable): \_\_\_\_\_

Full title of protocol: \_\_\_\_\_

1. Has your right to conduct research been suspended or cancelled by a funding or regulatory agency or have you lost the right to practice in your field?  No  Yes **[if yes, attach a report with explanation]**
2. Have any problems arisen during the course of research (including interruption of study at any site) occurred at any study site?  
 No  Yes **[if yes, append details]**
3. 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?  
 No  Yes **[if yes, append details with a plan for how you will inform project participants]**
4. This question applies only to experimental intervention studies. Have any serious adverse events related to experimental devices/medications/procedures occurred at SMHC or any other study sites?  
 No  Yes **[if yes, append details]**
5. If you answered yes to any of questions 2, 3 or 4, have you made any modifications/amendments as a result?  
 Not applicable  No  Yes **[if not, explain why not below]**

\_\_\_\_\_  
\_\_\_\_\_

6. Check off below any documents amended since initial approval/last interim review. Include the revised version of each document with the changes highlighted.

**Amendment made to:**

- Protocol
- Human Subjects Review Summary
- Consent Form
- Other (advertisement, questionnaire, budget, personnel)
- No amendments made

**Revised Documents Enclosed:**

- No  Yes Dated: \_\_\_\_\_
- No  Yes Dated: \_\_\_\_\_
- No  Yes Dated: \_\_\_\_\_
- No  Yes Dated: \_\_\_\_\_

7. Signatures:

\_\_\_\_\_  
Principal Investigator Date (yyyy/mm/dd)

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