MOUNT LEBANON HOSPITAL	*MEDICAL ADMINISTRATION*	CODE : MA-F-32	
	ETHICS' COMMITTEE CLINICAL TRIALS PROGRESS REPORT	*Edition -3-*	*Page 1/2*

□ Interim and progress report □ Number _____ □ Period _____
□ Final and progress report (should be submitted upon the closure of the study)

Principal Investigator:

Study Title:	**Date of IRB approval received:**	
	First Patient In:	
	Number of Participants recruited to date:	
Ethics Reference No:	**Report received:**	

1. Commencement and termination dates

Has the study started? (First patient screened)	□ Yes □ No
If yes, what was the actual start date?	……
If no, what are the reasons for the study not commencing? What is the expected start date?	…… …… …… Date: ……
Has the study finished?	□ Yes □ No
If no, what is the expected completion date?	Date: ……
If you do not expect the study to be completed, give reason (s)	…… ……

2. Site Information

Do you plan to increase the total number of sites proposed for the study? If yes, how many sites do you plan to recruit?	□ Yes □ No ……

3. Recruitment of participants

Number of participants planned and actually enrolled in this trial:	(a) Planned: …… (b) Actual:……
Number of participants completing the trial:	
Total number of withdrawals from study to date due to: (a) Withdrawal of consent (b) Loss to follow –up (c) Death (where not the primary outcome) (d) Serious adverse event (e) Inefficacy	number of withdrawals from study to date due to: (a) …… (c) …… (d) …… (e) …… (f) …… Total study withdrawals:
Number of treatment failures to date (prior to reaching primary outcome) due to: (a) Adverse events (b) Lack of efficacy (c) Non-Compliance	(a)…… (b) …… (c) …… Total treatment failures:
Have there been any serious difficulties in recruiting participants?	
If yes, give details:	
Do you plan to increase the planned recruitment of participants into the study?	

4. Safety of participants

Have there been any unexpected serious adverse events (SAEs) related to the investigational product in this study, or in any other study or source of information?	
Have these SAEs been notified to the Ethics Committee?	
Have any concerns arisen about the safety of participants in this study?	

5. Amendments

Have any substantial amendments been made to the trial since the last report ?	
If yes, please give the date of the amendment and the number of each substantial amendment made	

6. Serious breaches of the protocol

Have any serious breaches of the protocol occurred during the year? If yes, please enclose a report of any serious breaches not already notified to the committee.	

7. Other issues

Are there any other developments in the study that you wish to report to the Ethics Committee?	
Are there any ethical or regulatory issues on which further advice is required?	

ANY OTHER COMMENTS: *(use additional pages if necessary)*
(If estimated date of conclusion has changed or study has been terminated before completion, please explain, eg recruitment slower than anticipated and why)

_____

_____

Have any preliminary or final results from the study been presented? Please give details and <u>provide</u> a summary or abstract. If study is completed and there are no plans for publication, please explain.

_____

_____

DECLARATION:

I _____ (Principal Investigator) declare that this is a true and accurate record of my research project as at _____ (date).

Signed_____

NB: Failure to provide a timely report may result in withdrawal of ethical approval of the project.