RESEARCH ADVISORY COUNCIL
PHARMACY INFORMATION LETTER

Proposal Title: _____

RAC #: (if available) _____ **Principal Investigator:** _____

A This part is to be completed by the Principal Investigator

1 ***Please itemise all the drugs the study subjects will receive including drugs used for routine medical care and placebo (Rou = routine medical care: Exp: = Experimental) (if more space is needed, use copies of this form)***

Drug Name	**Nusinersen**		**Nusinersen**							
	Ro	**Exp**	***R***	**Exp**	***R***	**Exp**	***Rou***	**Exp**	***Rou***	**Exp**
Dose										
Administration Route										
Administration Frequency										
Length of treatment										
Drug Status *										
Number of patients										
Provider: Hospital or Sponsor (Identify Sponsor)										
Total Drugs Required (Pharmacy will calculate)										
(For Pharmacy Use) Medication Cost	***Ro***	**Exp:**	***R***	**Exp:**	***R***	**Exp:**	***Rou:***	**Exp:**	***Rou:***	**Exp:**
Research Pharmacist time					**_____(hrs) X**		**_____SR/hr**		**= SR _____**	

2 If this a randomised study, who is responsible for Randomization? _____

3 Over what period of time do you intend to accrue the patients? _____

***** The Pharmacy must seek approval through the MOH in order to import drugs. Approval of the proposal by the RAC does not guarantee that the drugs will be approved and/or released by the MOH. Being a registered or investigational drug in any of the five reference countries (USA, Canada, UK, Sweden, Saudi Arabia) would help in obtaining MOH approval.

Please use the following abbreviations: **HF** – on Hospital Formulary; **MOH** – registered by the Saudi Ministry of Health; **USA** – registered in USA; **CA** – registered in Canada; **UK** – registered in UK; **SW** – registered in Sweden; **USAI** – being investigated in USA; **CAI** – being investigated in Canada; **UKI** – being investigated in UK; **SWI** – being investigated in Sweden.

Principal Investigator:

RESEARCH ADVISORY COUNCIL
PHARMACY INFORMATION LETTER

Proposal Title: _____

RAC #: (if available) _____ **Principal Investigator:** _____

Name (print) _____ **Signature:** _____ **Date:** _____

RESEARCH ADVISORY COUNCIL
PHARMACY INFORMATION LETTER

Proposal Title: _____

RAC #: (if available) _____ **Principal Investigator:** _____

B **<u>This part is to be completed by the Pharmacy:</u>** (check appropriate box(es) and complete)

☐ The Pharmacy Department has assigned a Research Pharmacist to provide information and assistance in the conduct of this proposal. If you have any questions please call the Office of Research Affairs at 32937.

The Pharmacy will provide the following:

I Drug keeping & dispensing
II Preparation of Drug
III Drug Information (physician, nurse, pharmacist etc.)
IV MOH Permit for import, release from Custom
V Patient counseling for drug information, compliance, medication handling, and return of unused products (if required)
VI Maintain and submit to RAC, upon completion/termination of the study, investigational drug records of:
  a) inventory; delivery to KFSH&RC: Date, amount, lot #, expiration date etc,
  b) use by each study subject
VII Follow the trial randomisation procedure
VIII Supply the drugs listed on page 1 of this form

☐ The Pharmacy will be happy to provide the above, provided the following issues have been satisfactorily addressed:

1
2
3
4

☐ The Pharmacy will not be able to assist with this project due to the following:

_____

_____

☐ Total Pharmacy cost (routine care) _____ SR Total Pharmacy cost (experimental) _____ SR

This form page completed by:

Name (print) _____ Signature: _____ Date: _____

Approved by: _____ Date: _____
Head of Pharmacy