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|  <small>MOUNT LEBANON HOSPITAL GHANOUK MEDICAL CENTER</small> | <i>MEDICAL ADMINISTRATION</i> | | CODE : MA-F-35 | |
| | CLINICAL TRIAL APPLICATION FORM IN HUMAN SUBJECTS | | <i>Edition</i> -3- | <i>Page</i> 1/3 |

Registration N°. (*Office use only*)

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| | | |
| <i>Code</i> | | |


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| | | | |
| <i>year</i> | | | |

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| | | |
| <i>No</i> | | |

TRIAL TYPE: Interventional

Non-Interventional/Observational

| | |
|--|---|
| PROTOCOL CODE NAME/NUMBER: | INVESTIGATIONAL PRODUCT (IP): <input type="checkbox"/> Medical Device <input type="checkbox"/> Drug <input type="checkbox"/> Other, specify ----- |
| PROTOCOL TITLE: | |
| PRINCIPAL INVESTIGATOR (S) | |
| NAME & TITLE: | |
| DEPARTMENT: | |
| PHONE NUMBER: | |
| EMAIL: | |
| ADRESS FOR CORRESPONDANCE: | |
| OTHER INVESTIGATOR (S) | |
| NAME & TITLE: | |
| DEPARTMENT: | |
| PHONE NUMBER: | |
| EMAIL: | |
| ADRESS FOR CORRESPONDANCE: | |
| OTHER PARTICIPATING INVESTIGATOR(S)- HOSPITAL(S) IN LEBANON: | |
| <ul style="list-style-type: none"> • • • • | |
| TRIAL'S SPONSOR | APPLICANT ON BEHALF OF THE SPONSOR (if applicable) |
| Name of company: | Name of company: |
| Name of the contact person: | Name of the contact person: |
| Address: | Address: |
| Telephone & fax number: | Telephone & fax number: |
| e-mail: | e-mail: |

| | | | |
|---|--|----------------|-------------|
|  MOUNT LEBANON HOSPITAL GRANDS MEDICAL CENTER | <i>MEDICAL ADMINISTRATION</i> | CODE : MA-F-35 | |
| | CLINICAL TRIAL APPLICATION FORM IN HUMAN SUBJECTS | Edition -3- | Page 2/3 |

TESTED IP (Investigational product)

IP with a market authorization? Yes No

IP active substance origin:
specify (chemical, biological/ biotechnological, blood derived..)

Comparator, if any, (reference drug or placebo), give details:

TRIAL INFORMATION (For interventional trials)

Trial phase: I II III IV

If phase I, is this a first administration to humans? Yes No

Has the trial been submitted to other countries authorities? Yes No

If yes,

- Which country did authorize the trial?
- Which country did not authorize the trial?
- Reason for non-authorization:

Is the trial prepared to be submitted to other countries authorities? Yes No
If yes, specify which countries:

Number of trial's participating centres in each country:

Trial expected start and end dates in Mount Lebanon Hospital (from first subject in to last subject out):

TRIAL INFORMATION (For non-interventional trials)

Trial type:
 Phase IV
 Other, specify

POPULATION OF TRIAL SUBJECTS IN LEBANON

Number of patients to be included in Lebanon (_____) and at Mount Lebanon Hospital (_____)

Subjects below 18 years? Yes No
If yes specify age:

Women of child baring potential with no efficient contraception imposed by the protocol? Yes No


Pregnant women? Yes No

Other vulnerable population? Yes No

If yes, specify:

Duration of participation to the trial per patient:

Number of visits to the trial centres per patient:

| | | | | |
|---|--|--|-----------------------|--------------------|
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| | CLINICAL TRIAL APPLICATION FORM IN HUMAN SUBJECTS | | <i>Edition</i> -3- | <i>Page</i> 3/3 |

Reserved for EC use

| Documents needed | Documents submitted | | |
|---|---------------------|----|----|
| | Yes | No | NA |
| Investigator's submission letter | | | |
| Trial protocol | | | |
| Subject information and consent form | | | |
| Case report form | | | |
| Patient card | | | |
| Other patient document (diary...) | | | |
| Recruitment Advertisement | | | |
| Investigator brochure or summary of product characteristics (if study drug is marketed and used according to the terms and conditions of its SPC) | | | |
| Trial insurance | | | |
| Principal Investigator updated CV (MA-F-36, unless sponsor's or CRO's template used) | | | |
| Co-Investigators updated CV (MA-F-36, unless sponsor's or CRO's template used) | | | |
| Other documents: | | | |
| File Complete Yes <input type="checkbox"/> No <input type="checkbox"/> ; If No, missing documents, | | | |
| Acknowledgement of receipt: | | | |
| Name: _____ Signature: _____ Date: _____ | | | |