**ETHICS APPROVAL REQUEST FORM**

**Application for Research on Human Subjects**

**Submit a filled and signed copy of this document to the Research Ethics Committee (REC) at INSPECT-LB. Attach any other forms and documents required/needed.**

To approve research involving human subjects, the REC must determine the following points:

* The research design is scientifically acceptable;
* The risks associated with the research are reasonable and justified by the expected benefits;
* The participants’ informed consent is obtained from the subjects or their legally authorized representatives;
* The privacy of all participants is respected;
* The confidentiality of the collected data is protected;
* An adequate monitoring will be performed to ensure the safety of participants;
* Vulnerable subject populations will receive additional protection; and
* The selection and recruitment procedures are equitable and correct.

# **Study Identification**

**Please answer all relevant questions that will reasonably help to describe your study or proposed research.**

## 1.0 Study Title:

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## 2.0 Principal Investigator:

|  |  |
| --- | --- |
| **Last Name:** | **First Name:** |
| **Title:**  | **Institution:**  |
| **Phone:**  | **E-mail:**  |

## 3.0 Study **Coordinator**

***The study coordinator can be the same person as the principal investigator.***

|  |  |
| --- | --- |
| **Last Name:**  | **First Name:** |
| **Title:**  | **Institution:**  |
| **Phone:**  | **E-mail:**  |

## **4.0 Study Co-investigators**

Include all people responsible for the design and conduct of the study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Full Name** | **Title** | **Affiliation** | **Contribution** | **E-mail** |
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| 8.  |  |  |  |  |
| 9.  |  |  |  |  |

***All collaborators are required to provide a signed Consent and Declaration of Interest Form (found in Appendix) and an updated Curriculum Vitae.***

## 5.0 Time frame and location of the study

### 5.1 Anticipated study start date:

Click or tap to enter a date.

### 5.2 Anticipated study end date:

Click or tap to enter a date.

### 5.3 Specify site where the study will be conducted

**List the locations of the proposed research, including recruitment activities. Provide name of institution, facility or organization, locality, or province as applicable**:

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## 6.0 Funding

### 6.1 Is the proposed research funded?

***(Grant, sub-grant, contract, internal funds, sponsor, donation, or other source of funding)***

[ ] Yes [ ]  No

6.2 For funded research, specify the funding source/Sponsor name:

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## 7.0 Research Methods and Procedures

**Please check from the list below, research methods involved in the proposed study. Select all that apply.**

[ ]  Food, nutrition, and nutraceuticals

[ ]  Internet-based interaction with participants (excluding internet surveys or data collection over internet without human interaction)

[ ]  Interviews and/or focus groups

[ ]  Materials created by participants (e.g., artwork, writing samples, photo, voice, etc.)

[ ]  Participant observation

[ ]  Surveys and questionnaires (including internet surveys)

[ ]  Secondary use of information (analyzing data previously collected for another purpose)

[ ]  Biohazardous substances

[ ]  Data registries and/or biobanking (collection of samples to put in a biobank/sample repository)

[ ]  Clinical trial

[ ]  Collection of human biological materials (i.e., blood, tissue, etc.)

[ ]  Drugs, medical devices, biologics or vaccines and/or natural health products

[ ]  Radiation: any test or procedure that may involve exposure to radiation (including chest x-ray)

[ ]  Stem cell research

[ ]  Chart review/review of health data (i.e., paper charts, electronic health records, or administrative health data).

 ***Select this ONLY if your application SOLELY involves a review of paper charts/electronic health records/administrative health data to answer the research question. If you are enrolling people into a study and need to collect data from their health records in addition to other interventions, then you SHOULD NOT select this box.***

[ ]  Secondary use of human biological materials

[ ]  Research on individual or groups characteristics or behavior such as perception, cognition, motivation, identity, language, communication, cultural beliefs, or practices and social behavior

[ ]  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## 8.0 Study design

**Which of the following categories applies to the study?**

[ ]  Case report (> 3 case series) [ ]  Retrospective study (descriptive)

[ ]  Randomized controlled study [ ]  Cohort study

[ ]  Cross-sectional study [ ]  Case control Study

[ ]  Investigational drug or device (non-approved for clinical use): attach investigator’s brochure

[ ]  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## 9.0 Type of research

**Please check the box which most closely describes the type of research for this study:**

[ ]  Biomedical Research on human participants that is not diagnostic or therapeutic

[ ]  Clinical Research on or for the treatment of patients

[ ]  Health Services Research on how to improve the health care system

[ ]  Population Health Research on factors affecting health status

[ ]  Clinical Epidemiology Research on scale validation and screening and diagnostic tools

## 10.0 Academic Program

**If this research is required for completion of an academic program, specify:**

[ ]  Master’s degree [ ]  Doctorate [ ]  Residency

[ ]  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# **Summary of the study**

**Provide a lay summary of your proposed research, which would be understandable to the general public. This summary, different from that provided in the scientific proposal, must not exceed 500 words, and should include:**

1. Scientific context

2 Hypothesis/aims

3. Experimental design, subject selection/recruitment, procedures involving human subjects

4. Justification of the involvement of human subjects

5. Description of risks and benefits

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# **Informed Consent Process**

**Please attach the consent form(s) that will be used in the proposed study**

1.0 Specify all languages to be used for the informed consent form:

[ ]  Arabic [ ]  English [ ]  French [ ]  Other. Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.0 Describe the setting in which the informed consent will be obtained:

2.1 Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### 2.2 Procedure:

**How will consent be obtained?**

 [ ]  Free (self-reading and signature) [ ]  Guided (reading and understanding of content)

 [ ]  Individual [ ]  Collective

## 3.0 Persons who will obtain informed consent from the subjects’ participants

***Describe who will administer the consent process and whether or not they have a direct relationship with the participant:***

|  |  |  |  |
| --- | --- | --- | --- |
| **Full Name** | **Qualifications and role in the study** | **Training completed** | **Direct relationship with participant** |
| 1.  |  | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 2.  |  | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 3.  |  | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 4.  |  | [ ] Yes [ ] No | [ ] Yes [ ] No |

## 4.0 If the person obtaining consent have any relationship with the patient, please indicate ways of protecting against undue influence or coercion.

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## 5.0 Will you request a waiver of written informed consent or omission of any requirements (e.g. non-disclosure of information to the subject)?

 [ ]  No [ ]  Yes, please justify:

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## 6.0 Will participants incapable of providing consent be enrolled in the study?

 [ ]  No [ ]  Yes, please describe the procedure:

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# **Subject Selection and Recruitment**

1.0 Number of subjects to recruit: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.0 Identification and recruitment of subjects:

*Describe the procedure, the location/setting, and period* ***(e.g., provide a script for personal or phone contact).***

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3.0 Will you use advertisements to solicit participants? [ ]  No [ ]  Yes

If yes, provide a copy of the advertisement and choose the applicable category from below:

[ ]  Letter [ ]  Phone

[ ]  E-mail [ ]  Internet

[ ]  Posters [ ]  Publication

[ ]  Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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4.0 Describe the subject population ***(Inclusion criteria)***

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5.0 Define the exclusion of subjects ***(Exclusion criteria)***

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## 6.0 Vulnerable groups

### 6.1 Specify whether any vulnerable group(s) will be included in the proposed research:

[ ]  Children/minors [ ]  Elderly

[ ]  Prisoners [ ]  Subordinates/employees at institution

[ ]  Students [ ]  Others, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  No vulnerable groups will be included in the study

### 6.2 Subjects with cognitive impairment are considered a vulnerable sample; describe why it is necessary to include them in the study if you must include them.

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# **Specimen Collection**

## Blood drawing

|  |  |  |  |
| --- | --- | --- | --- |
| **Amount per drawing** | **Frequency** | **Total amount** | **Setting of blood drawing*****(hospital, home, laboratory, etc.)*** |
|  |  |  |  |

**Specify:**

The person responsible for blood drawing: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The setting of blood manipulation and storage of samples/specimens: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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The setting of laboratory tests of blood analysis: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Method, conditions of transportation, and persons in charge: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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2.0 Other tissues; describe:

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3.0 If genetic tests are to be done, describe and use genetic template language in informed consent form:

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# **Research Risks**

## 1.0 Describe the potential risks associated with the study.

***Risk includes physical, psychological, social (potential stigmatization e.g. HIV), legal (research on illicit behavior) or financial (cost of study). Summarize the known or anticipated risks/harms of the study.***

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## 2.0 Are there other methods to run the research that might minimize these risks?

***Describe and justify the reasons for not using them.***

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## **3.0 Will ionizing radiation be used as part of this study?**

 [ ]  No [ ]  Yes

4.0 Risk Mitigation plan

***Is there a reasonable expectation that study data collection tools could uncover serious anxiety or depression, or suicidal intentions, or evoke strong emotional responses to past abuse or trauma? If so, provide the plan for mitigating these risks:***

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## **5.0 Disadvantages and risks to the participants**

***Will these disadvantages and risks be mentioned to the participants?***

 [ ]  No [ ]  Yes ***(if yes, please attach the informed consent)***

6.0 Data Security and Participants Protection

### 6.1 Privacy of participants

***Describe how you will ensure that privacy of participants will be respected during the research, or during scientific publications and presentations.***

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### 6.2 Access to the data

***Identify the people (and positions) that will have access to the data.***

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### 6.3 Ensure confidentiality

***How will confidentiality of the data be maintained? Describe how the identity of participants will be protected both during and after research?***

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### 6.4 Retention of Research Records and Documents

***How will the records/documents be disposed of after completion of the study? Specify the time frame and describe how any data collected will be stored before disposal, e.g., digital files, hard copies, audio recordings, or other. Specify the physical location and how it will be secured to protect confidentiality and privacy (e.g., documents kept in a locked filing cabinet or computer files encrypted)***

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## 7.0 What are the criteria for suspending or stopping a participant in the research project?

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## 8.0 If this is a therapeutic trial, list the therapeutic alternatives.

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## 9.0 Use of placebo

***If this study involves the use of a placebo, the risk related to the placebo must be mentioned in the protocol, and the informed consent form. Check the applicable justification for the use of a placebo:***

[ ]  No alternative standard therapy

[ ]  Alternative standard therapy exists but risks of placebo are minimal

[ ]  Alternative therapy exists, risks of placebo exceed the minimal, but plans for intervention exist (Describe plans for intervention if any adverse effect occurs)

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[ ]  If none of the above is applicable, justify the use of placebo

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# **Benefits for the participants**

Describe the potential benefits of the study for the subject. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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***If no direct benefits are expected, state it and include it in the consent form. Note that monetary compensation is not considered a benefit.***

# **Compensation or Costs to Subjects**

## 1.0 Expenses for participants

***There are very particular circumstances under which study participants may be responsible (either directly or via their insurance) for covering some study-related expenses. Describe these added expenses and provide a justification. (e.g. extended hospitalization, extra laboratory tests, travel…)***

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## 2.0 Will participants be compensated for their participation?

[ ]  No [ ]  Yes. If yes, provide details:

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## 3.0 Side effects compensation

If the research will cause side effects or complications that may affect the participant’s health, is there a protocol for:

* Medical treatment and follow up;
* Compensation according to the expectation

 [ ]  No [ ]  Yes, justify:

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# **Conflict of Interest**

Are there any real, perceived, or potential conflicts of interest among the principal investigator, co-investigators, and/or their immediate family members? [ ]  No [ ]  Yes

***If yes, please disclose any personal or financial interests in the research and their extent by filling the Consent and Declaration of Interest Form, and providing a summary of these conflicts, and the way they will be managed.***

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# **References**

**Please list between five to six relevant publications that, in your opinion, would be helpful to the REC in reviewing the proposed study.**

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**Principal Investigator’s Assurance Statement**

1. I certify that the information provided in this application is accurate and complete.
2. I understand that, as principal investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights, safety, and welfare of the human participants, and strict adherence to the study protocol and any conditions or modifications stipulated by the REC.
3. I will submit modifications of the protocol and/or the informed consent form and/or any other documents to the REC for approval prior to applying those changes in the study.
4. I agree to abide by the policies and procedures of the REC regarding the protection of human subjects, including, but not limited to:
* Ensuring that all personnel involved in the study are well trained on the ethics of research with human subjects.
* Ensuring that the study will be conducted by qualified personnel only.
* Obtaining informed consent from participants or their legally appointed representatives or guardians, using the informed consent form stamped with approval by the REC, and providing a copy of the signed form to the subject.
* Reporting adverse events or other unexpected problems and risks involving human subjects to the REC promptly.
* Complying with REC decision to stop or discontinue the research promptly.
* Obtaining approval to continue with the study after the end of the approval period by submitting a request for renewal before the study expires. I understand that if I fail to apply for renewal, the study will automatically expire, and all activity must cease until the REC approval is granted
* Maintaining accurate and complete research records, including all informed consent documents, for at least three years from the date of study completion.
* Fully informing the REC of all regions where participants will be recruited for this study.
* Filling a “Patient enrollment form” for patients recruited in clinical trials and maintain a copy of this form in the corresponding medical record.

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**Principal Investigator’s Signature** **Date**