Project title: Insert project title
Principal Invesitgator: Insert name of principal investigator
Informed Consent Version Date: Insert date of submission

Note: You can add or remove sections as suitable for your study. Please delete instructions in red once you complete the form.

Consent Form

INTRODUCTION*

You are cordially invited to participate in our research study titled « ….. ». You have been chosen as a potential participant based on your alignment with our research criteria. We kindly request that you carefully review this document, address any inquiries you may have, and reach a decision at your own pace. We encourage you to engage in discussions about your decision with your family, friends, and medical professionals.

WHAT IS THE PURPOSE OF THIS STUDY?*

This study aims to elucidate the objectives of our research. You have been chosen to participate in this study due to your specific qualifications, condition, age, or healthy status. [Please inform the participant if this project is part of a Master's or PhD].

WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH STUDY?*

It is crucial that you carefully review and comprehend the following points applicable to all study participants:

- Voluntary Participation: Your involvement in the study is entirely voluntary, and declining to participate will not impact your rights or benefits.
- Potential Benefits: While participation may or may not directly benefit you, your involvement may contribute valuable knowledge that could benefit others.
- Right to Withdraw: You have the right to withdraw from the study at any time without facing any penalties or losing any usual benefits.

Further details regarding the study's nature, potential benefits, risks, discomforts, and other pertinent information are outlined below. Should any new information arise during the research that may affect your participation, you will be promptly informed. We strongly encourage you to address any questions or concerns you may have about the study with the staff members who

will provide further explanation, as well as with your own advisors, before consenting to participate.

WHO IS IN CHARGE OF THIS STUDY?*

The lead investigator of this study is..... The research is being sponsored by .....

WHO CANNOT PARTICIPATE IN THIS STUDY?*

You cannot be in this study if any of the following apply to you: .....

WHAT IF I AM PRESENTLY PARTICIPATING IN ANOTHER RESEARCH STUDY?

Are you presently participating in any other research studies? ☐Yes ☐No
If YES, please state which study(ies):

While participating in this study, you should not take part in any other research project without approval from the people in charge of each study. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?*

About insert number people will take part in this study.

WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?*

If you agree to be in this study, you will undergo the following tests and procedures:
[Please provide an overview of the study's requirements, including the procedures involved and the specific actions the participant will undergo if they decide to participate. Consider incorporating a simplified diagram or timeline to illustrate the participant's obligations. Clarify whether the participant will be engaged at home, in a hospital setting, or as an outpatient. If the

study aims to compare interventions, ensure all procedures are outlined, including those deemed standard].

HOW LONG WILL I BE IN THE STUDY?*

We anticipate that you will be in the study for…. of months/weeks, until a certain event or date. However, it is your right to withdraw at any time during the study.
The investigator may decide to take you off this study if it is believed to be in your best interest, you fail to follow instructions, new information becomes known about the safety of the study, or for other reasons the investigator or sponsor believes are important.

WHAT ARE THE RISKS AND SIDE EFFECTS OF THIS STUDY?*

If you choose to participate in this study, it's important to understand that there may be potential risks involved, which will be thoroughly explained to you by the research team. We encourage you to ask any questions you may have and to discuss any concerns with your family and friends before making a decision. Possible risks and side effects associated with this study include:

[List all foreseeable physical and non-physical risks, such as the inability to work, emotional distress, etc., as well as discomforts like prolonged sitting, confinement, reliving painful memories, multiple injections, etc. Describe how these risks will be managed, including their severity and reversibility. Additionally, include any social, legal, or financial risks that may arise from participation in the research].

[If applicable]:
Please tell the investigator about all medications including over the counter drugs or herbal supplement you are taking, even if you don't think they are important.

[If applicable - for research involving genetic or related testing, participants must be informed of any risks associated with the genetic information that may result]:

In this study, genetic testing will be conducted. Risks associated with genetic testing include the potential misuse of personal genetic information. Although rare, misuse of such information has led to issues related to employment, life and health insurance, and other benefits or entitlements. Additionally, participation in a genetics study may cause psychological distress or

tension within family dynamics. While every reasonable effort will be made to safeguard your personally identifiable information to prevent misuse, there can be no absolute guarantees. Even with confidentiality measures in place, disclosing genetic testing history could lead to denial of benefits or other forms of discrimination.

For further details regarding risks and side effects, please do not hesitate to reach out to [insert name of the investigator].

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?*

[If there is no intended benefit to any participants, insert the following statement: **"This study is not designed to provide direct benefits to any participants."**].

WHAT ABOUT CONFIDENTIALITY?*

[This section must outline how all the confidential information and/or materials will be treated, stored, and maintained, as well as the duration for which they will be retained, and the procedures for disposal at the conclusion of the study period.]

Your personal health information (PHI) will be handled with utmost confidentiality, in accordance with applicable laws. Your identity will not be disclosed in any publications arising from this study. Access to your PHI and any information obtained during the study will be strictly limited to authorized personnel within the research team. Measures will be in place to ensure that your confidentiality is preserved at all times.

At the conclusion of the study, all confidential information and materials will be securely stored for a period specified by regulatory guidelines. Subsequently, they will be disposed of using appropriate methods to safeguard confidentiality and privacy.

If you choose to participate, you are free to withdraw your permission for the use and sharing of your health information at any time. You must do this in writing. Inform insert Investigator name via email (insert email address) and let (him/her) know that you are withdrawing from the research study.

Project title: Insert project title
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WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?*

You (choose one: will/will not) be paid for being in this study. [If participant is compensated, state payment schedule/amount].

WHAT ARE THE COSTS?*

You do not have to pay anything to be in this study. You will not be charged for (insert any appropriate tests, procedures, medications, etc.) that are part of this research study.

WHAT IF I'M INJURED OR BECOME ILL DURING THE STUDY?

We are committed to minimizing the risk of injury or illness during your participation in the study. In the event of an injury, illness, or any harm arising from or related to the study, (please specify the procedure that will be followed in such instances).

WHAT ARE MY RIGHTS AS A PARTICIPANT?*

You have the right to:

- Receive information about the nature and purpose of the study.
- Be provided with a clear explanation of the study procedures.
- Receive a description of potential risks, discomforts, and benefits associated with participation.
- Be informed of any alternative options available, including medications or devices, along with their potential risks, discomforts, and benefits.
- Ask any questions you may have about the study.
- Decide whether or not to participate without coercion or deception.
- Receive a copy of this consent form.
- Withdraw from the study at any time without repercussions.

Project title: Insert project title
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By signing this form, you do not waive any legal rights as a research participant. You may opt not to participate or withdraw from the study at any point. Your standard care will not be affected, and you will not lose any benefits. We will also inform you of any new information that may impact your decision to participate in the study.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?*

For questions about the study or a research-related injury, please contact the lead investigator, insert name at insert contact number and insert email address. If you are having a medical emergency, you should go directly to the nearest emergency room.

[Please insert contact information for any research team member, as needed.]

For questions about your rights as a research participant, please contact the ESI-SBA Office at:

Email: …..@esi-sba.dz

[if applicable]

CONSENT FOR STUDIES INVOLVING GENETIC MATERIAL (DNA/RNA)

To safeguard against breaches of confidentiality, all DNA samples will be coded and stored without any identifying information. A strictly confidential record of these samples will be maintained, securely locked in designated areas. Every effort will be made to protect your personal genetic information within the bounds of legal regulations. Medical records of research study participants will be stored and managed in accordance with legal requirements. Your identity will not be disclosed in any reports or publications resulting from this study.

Project title: Insert project title
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[if applicable]

AGREEMENT FOR THE USE OF BIOSPECIMENS AND DATA FOR FUTURE RESEARCH

Do you agree to the anonymous use of your biospecimens, anthropometric, demographic and clinical data collected during this study, in future research studies?

☐ I permit anonymized (samples cannot be linked to subject) use of my biospecimens, anthropometric, demographic and clinical data for other studies without contact.

☐ I permit further contact to seek permission to do further studies on my biospecimens, anthropometric, demographic and clinical data.

☐ I do not allow use of my biospecimens, anthropometric, demographic and clinical data for further studies.

SIGNATURES*

As a representative of this study, I have thoroughly elucidated the purpose, procedures, potential benefits, and risks associated with this research study. I have addressed any questions raised to the individual's satisfaction.

_____	_____	_____
Name of Person Obtaining Consent	**Signature of Person Obtaining Consent**	**Date of Signature**

I, the undersigned, have been thoroughly informed about the purpose, procedures, potential benefits, and risks of this study. I have received a copy of this consent form and have had the opportunity to ask questions before signing. I understand that I can ask additional questions at any time. I voluntarily consent to participate in this study. I retain the right to withdraw from the study at any time without needing to provide justification, and I understand that withdrawing will not impact my future treatment or medical care. I agree to collaborate with (name of principal investigator) and the research staff, and I commit to promptly reporting any unexpected or unusual symptoms experienced during the study.

_____	_____	_____
Participant's Name	**Participant's Signature**	**Date of Signature**

Project title: Insert project title

Principal Invesitgator: Insert name of principal investigator

Informed Consent Version Date: Insert date of submission

_____ _____

Signature of Witness (if applicable) **Date of Signature**

_____ _____

Signature of Legally Authorized Representative (When Appropriate) **Date of Signature**

_____

Relationship to Participant (When Appropriate)

Note: if your study includes anonymous participation (ex: interviews/questionnaires…etc.), please remove “Participant’s name”.