

**The University of Jordan**

**Deanship of Scientific Research**

**Informed Consent Form**

Informed consent is a basic research process that aims to achieve the basic principles of scientific research ethics on humans: respect for individuals, justice, and beneficence. An informed consent form must be used for all research studies in which human subjects participate directly and there is actual communication with the researcher(s), including collecting data, performing procedures or interventions of any kind, or conducting a paper or electronic questionnaire or interviews. This form must contain the statements mentioned in the table below (compulsory and optional statements), making sure that the research participant is aware of these elements, and the subject must be given a copy of the paper form while keeping a signed copy with the researcher (as in the attached examples).

Please ensure that the informed consent form contains the following elements by answering (yes), (no), or (not applicable), and attach it with all other documents related to the study.

It should be noted that the study tool (such as a paper or electronic questionnaire) should include an introduction to the study in addition to the compulsory information mentioned below, and then a question of whether the individual wishes to participate or not should be stated.

|  |  |  |  |
| --- | --- | --- | --- |
| **Compulsory statements** | **Yes** | **No** | **N/A** |
| Name of the principal investigator |  |  |  |
| Phone number |  |  |  |
| E-mail |  |  |  |
| Study Title |  |  |  |
| A simplified description of the study and its main objectives |  |  |  |
| A description of the procedures used in the study |  |  |  |
| The role and responsibilities of the participant |  |  |  |
| The expected duration of actual participation |  |  |  |
| An explanation of the expected risks, inconveniences, and troubles that are logically to occur to the participant in the study, regardless of their magnitude, especially for studies that require physical or psychological intervention, with detailed information on the procedures to avoid or mitigate those risks |  |  |  |
| A description of any expected benefits for study participants or others |  |  |  |
| An explanation of how to preserve the confidentiality and identity of the participants and their specific research outcome |  |  |  |
| Stating the means of communication with the person or persons authorized to answer inquiries related to the study and the rights of the participants, especially in case of an occurrence of a negative incident to the research subjects |  |  |  |
| A statement that participation in the study is voluntary and that refusing to participate does not entail a negative repercussion or deprivation of any benefits or rights, and that the participant has the right not to answer any question |  |  |  |
| A statement that the participant has the right not to withdraw from the study at any time without being subjected to punishment or deprivation of benefits, with an explanation of any consequences of the participant's decision to withdraw from the study |  |  |  |
| Clarification of the possibility of using the participants’ samples and information for subsequent studies by the researchers and their partners, after obtaining official and ethical approvals |  |  |  |
| In the event that the participant is considered among the vulnerable groups of society, a statement of how to obtain the consent of the participants or their legal guardians, in addition to all the above information |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Optional statements** | **Yes** | **No** | **N/A** |
| The expected duration of the study |  |  |  |
| A description of how to follow up on risks, address them, and how to provide appropriate compensation (for studies that include more than minimal risks) |  |  |  |
| An explanation of the availability and nature of medical treatment in the event of an injury, or how to obtain more information about it |  |  |  |
| A statement of any financial burdens on the participant, whether actual or potential, as a result of participating in the study |  |  |  |
| Indication of the possibility of the participants knowing the research results that are specific to them upon completion of the study |  |  |  |
| A statement that, under unforeseen circumstances, the researcher may disengage the research participant from the study |  |  |  |
| A statement of how to deal with any critical research results that may affect the health of the participants or their decision to discontinue their participation |  |  |  |

**Informed consent form – example 1**

**(To be used in case of interventional studies)**

|  |  |  |
| --- | --- | --- |
| **Example**  **only** | **Consent for an adult to participate in a study**  **(Study title)** | **Participant’s copy** |

**We invite you to participate with us in a research study led by researchers at (School of.../the University of Jordan). We kindly ask you to read this document before you decide to participate.**

* What is the purpose of this study?

The study aims to…

* What is (mention the study topic in more details like: what are gene? What is disease x? what does y mean?)

Disease x is considered…

* What is your role?

We would like you to (for example: answer questions, donate a blood sample, etc.)

* What is your benefit from participating?

You may benefit by… OR there is no direct benefit to you but your participation will allow us to better understand…

* Are there any risks to you?

For example: blood collection may cause some pain, discomfort, bruising,…, personal information and identification may be leaked, etc.

* How are we going to collect (samples/information)?

For example: you may need to come to the center OR you need to answer a questionnaire.

* How will we preserve your privacy and confidentiality?

For example: we will use a coding system

* What if we need further information?

We will not need any further information OR if we need any further information, we may contact you by phone, etc.

* What if you decide to withdraw from the study?

You are free to withdraw from the study at any time without any negative repercussions. You may inform us of your decision by phone or e-mail (stated below).

* What if you have any further inquiries?

Feel free to contact us by phone or e-mail. Our contact information is:

**Researcher’s copy**

**Code:**

**I, the undersigned, declare that I have agreed to participate in a study (insert the title of the study) and that I am aware of the procedures involved. I am aware of the benefits and risks of participating. I also know whom to contact if I have any other questions or concerns. I also got a signed copy of this form.**

□ I agree to participate in the study.

□ I agree that the researchers can obtain additional information when needed by contacting me, my medical file, or my attending physician (note to the researcher: an optional clause that can be omitted).

□ I agree that the researchers will use (for example: my answers or samples (in the event of collecting a vital sample such as blood or saliva) and my information) in subsequent future studies while retaining all my rights, provided that the necessary approvals are obtained from the research ethics committees (Note to the researcher: optional sentence can be removed).

|  |  |  |  |
| --- | --- | --- | --- |
| **........................................** | **........................................** | | **....................** |
| Name | Signature | | Date |
| ........................................ | | ........................................ | |
| Phone number | | Alternative phone number | |

|  |  |
| --- | --- |
| ........................................ | ........................................ |
| Phone number | Name of an alternative person to contact |

|  |  |  |
| --- | --- | --- |
| **........................................** | **........................................** | **....................** |
| Name of a witness | Signature | Date |
| ........................................ | ........................................ | .................... |
| Name of a study member | Signature | Date |

**Informed consent form – example 2**

**(To be used for questionnaires)**

**Informed consent form**

Greetings,

I (name) - (professor / Ph.D. student / etc.) at the School of ... at the University of Jordan - am conducting a study entitled "-------", aimed at ---------. I kindly ask you to answer the following questionnaire accurately emphasizing that the answers will take you an estimated time (the expected time is set). I would like to state that the study has obtained the approval of the Institutional Review Board affiliated with the Deanship of Scientific Research at the university and that your participation in the study does not include any risks or harms (if there are risks, they must be stated and clarified, regardless of their insignificance). Your participation in the study has not benefits to you other than the service of scientific research (in the event that there are benefits for the participant, it must be stated accurately). Your participation in the study is voluntary and refusing to participate does not entail any negative repercussion or deprivation of any rights. You have the right not to answer any question or provide any information. You also have the right to withdraw from this does not entail any negative consequences.

I would also like to confirm that the information that will be obtained will remain confidential, will not be revealed to anyone other than the researchers, and will only be used for the purposes of scientific research, whether in this study or other studies of the researcher and will not be used for any other purposes except after obtaining the approval of the Institutional Review Board.

Do you consent to participate in the study?

( ) Yes ( ) No

• In case the participant is among the vulnerable groups of society, the question of consent to participate is directed to the legal guardian(s) as follows:

Do you consent to have your (for example: son) participate in the study?

( ) Yes ( ) No

In case of inquiries, you can contact the researcher(s) at:

phone:.........

Email: ........

**Thank you for your kind cooperation**