This annex composed of three parts

Annex II

Participant information sheet and consent form

(used in Clinical trial or clinical research)

Part I

Participant information sheet

Invitation: You are invited to participate in a research study under the title:
Conducted by (name and affiliation):
This research has been approved by the ethics committee of the Faculty of Pharmacy-MSA University Before you decide whether or not to participate in this study, please make sure that you are fully aware with the details of the study and what exactly is required from you and how would your participation affect the study. Please take the time to read the following parts before you sign the participant consent form. Your participation in this research is voluntarily and you are free to withdraw at any time, without providing reasons.
1-What is the purpose of this research? Write a brief outline on this study.
2-What is required from the participant? And why is he/she been invited?
3-What are the risks associated with the proposed procedure(s)?
4-What is the expected time for finishing the research?
5-How many times samples will be taken from participant? Will this sample be used in other researches? What is the expected time for storing this sample for research?
6- What are the expected benefits from this research for participants? For the community?

7- What are the reimbursements for participants?
I declare that I have read all the information in the participant information sheet and agree to participate in this research **Participant signature:**

If you find any problem in this research you can contact the following researcher	
Name: **Contact information:**	
Researcher declare that he/she is responsible for preserving the confidentiality of collected data and participant's personal information **Researcher signature:**	

Part II

Information on drugs or Medicinal products

This annex needs only to be completed if relevant to research. It should be completed when Drug or medicinal products or medical devices are used on Human participants.
Title of Research:

1. Is the study initiated /sponsored by pharmaceutical or other industrial company? Y/N

2. Does the study involve
   - Pre-marketing use of a product Y/N
   - A new use for marketed product Y/N
   - Studying the effect of marketed product? Y/N

3. If this is a clinical trial , what is the phase of this trial?

1) Drug and Medicinal product

a) Details of the medicinal product:

Approved Name	Active ingredient	strength	Manufacturer

b) Dosage regimen used:

Dosage & Frequency	Route

c) Is this dosage regimen
- The recommended dose regimen by the manufacture Y/N
- New dose regimen Y/N

d) What are the possible side effects?

e) What is the pharmacological action of this drug?

f) What are the arrangements for dispensing medicinal product? (please give details)

Part III

Patient Consent Form

Project Title
-I confirm that I have read and understand the Information Sheet for the above study, have had the opportunity to ask questions, and understand what I am expected to do as a volunteer. -I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my rights being affected. -I would like/not like my own results reported back to me, understanding that no interpretation may be possible. (answer yes/No) -I do/do not agree that photographs and video material recorded during the study may be used for illustration purposes in reports and any subsequent journal articles. This is on the understanding that, while every effort will be made to preserve my anonymity, this cannot be guaranteed. (answer agree/not agree) -I do/do not agree that samples provided during the study may be stored beyond the study duration for further research. I understand that these samples will be made anonymous and not traceable back to me. (answer agree /not agree)
Participant signature:
Certificate of Consent for children **I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for (child) to participate as a participant in this study and understand that I have the right to withdraw her/him from the study at any time without in any way affecting our care at this Centre.** **Print Name of Parent or Guardian _____** **Signature of Parent of Guardian_____** **Date _____**
Certificate of Consent for illiterate **I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.** **Print name of witness_____ AND Thumb print of participant** **Signature of witness _____** **Date _____**

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Consent Form has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year