**PARTICIPANT INFORMATION FORM GUIDELINES**

The informed consent process requires that prospective participants are provided with as much information as possible about a research project so that they and/or their legal guardians/advocates can make a genuinely “informed decision” about whether or not they want to participate in the project.

Information forms are typically provided to participants in written format, but can also be orally articulated, and are an essential part of the informed consent process. Thus, this document has been produced to serve as guidance towards adequately designing a participant information form. If you have any questions about this document please contact the College of Micronesia-FSM (COM-FSM) Institutional Review Board (IRB) at +691.320.2480 or IRBchair@comfsm.fm.

**General Information**

* The design of your participant information form should reflect the nature of the research study. Some information forms may therefore need to be a little more detailed than others, or may use graphics rather than merely text.
* Importantly, make sure that even after the information form has been read and consent obtained, the participant has the right to ask any further questions and should be provided with details on where to find further, appropriate information on the specific research area.
* All protocols and supporting documents, including information forms and consent forms, should state the version number and date in the header or footer. The date indicates when the documentation was finalised.

***Nota Bene:***

* *If an amendment to a document is made, the version number and date must also be amended.*
* *Version numbers and dates show how a document was developed, help to identify earlier versions if required and act as an aid to monitoring and audit.*
* *Failure to include them will slow the approval process as they will be sent back to the researcher for amendment.*
* It is essential that any logos, project titles, version numbers, dates, contact details, etc., are consistent across documents.
* Make provisions for participants who are not fluent in the language used in the information form and consider how to mitigate problems such as illiteracy. For example, you may choose to have an interpreter or translator available for participants who may not be fluent in the language used.
* **Studies involving children/vulnerable adults**: you may need to consider producing an alternative version of the information form which is more accessible and which can be discussed with the legal guardian (*e.g*. parent, caregiver etc.). This alternative version should however conform to the same purpose as other information forms in that the goal is to provide sufficient information, in appropriate detail, so that informed consent can be obtained.

**Recommended sections to include in your Participant Information Form**

1. **Title of Study**

Your study title should be the same on all related documents and should explain the study in simple English. If you have used a short title make sure that you quote this as well as the full title on your ethics application form.

1. **Version Number and Date**

All information forms should have a version number and date that is consistent with all corresponding documents (e.g. study plan / protocol, consent form).

1. **Invitation Paragraph**

Invite the participant to take part in the study and ensure that it does not sound as if the participant is being pressured or coerced:

*e.g.* ***You are being invited to participate in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and feel free to ask us if you would like more information or if there is anything that you do not understand. Please also feel free to discuss this with your friends, relatives, and GP if you wish. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to.***

***Thank you for reading this.***

1. **What is the purpose of the study?**

In lay terms, with all technical terms and acronyms defined, you should explain why the study is being done, e.g. the background, aims and objectives etc.

If it is not appropriate to inform participants of the purpose of the research at this stage, for example in the case where this may affect the behaviour of participants, please ensure that participants are fully debriefed at the end of the research. Please also enclose a debriefing form with your application for ethics.

1. **Why have I been chosen to take part?**

Briefly explain the reasons why and how you have chosen to invite participants and how many others will be taking part.

1. **Do I have to take part?**

It should be made clear that participation is voluntary and that participants are free to withdraw at any time, without explanation, and without incurring a disadvantage.

1. **What will happen if I take part?**

In lay terms, you should provide an explanation of exactly what will be asked of the participant and what will happen during the research. For example, you should explain clearly:

* + what the methods are
	+ who the researchers are
	+ who will be carrying out tests
	+ what the duration/frequency of the tests is
	+ what the participant’s responsibilities are

When writing this section, think about what details you would want to know if you were taking part in a research study.

Information should be displayed in an appropriate format for the population involved in the research, for example, pictorial/diagram/oral format rather than text may be more suitable for some.

Participants should be made aware if research involves any audio/visual recording and this should be made clear in both the information form and consent form.

Please note that if there is a possibility that the participant’s GP may need to be contacted, this should also be made clear in the information form and consent form.

1. **Expenses and/or payments**

Detail any expenses that might be available (e.g. for travel, refreshments, etc.) and any **reimbursement** for which participants may be eligible.

1. **Are there any risks in taking part?**

Please explain whether there are any perceived disadvantages or risks involved. Explain that if the participant should experience any discomfort or disadvantage as part of the research that this should be made known to the researcher(s) immediately.

1. **Are there any benefits in taking part?**

Any benefits (at the time of participation, or in the future) should be explained. If there is no intended benefit this should be made clear.

1. **What if I am unhappy or if there is a problem?**

All complaints should be handled through the COM-FSM Institutional Review Board complaints procedure. You should use something similar to the following to explain how complaints will be handled:

***“If you are unhappy, or if there is a problem, please feel free to let us know by contacting [Principal Investigator name and number] and we will try to help. If you remain unhappy or have a complaint which you feel you cannot come to us with then you should contact the COM-FSM Institutional Review Board at*** ***IRBchair@comfsm.fm******. When contacting the Institutional Review Board, please provide details of the name or description of the study (so that it can be identified), the researcher(s) involved, and the details of the complaint you wish to make.”***

1. **Will my participation be kept confidential?**

You should inform the participant how data will be collected, stored securely, and whether data will be anonymised, what data will be used for (whether for this specific project or also for future research), who will have access to these data, how long data will be stored for (please make sure you consult funder-specific guidance if applicable) and how data will be disposed.

**Disclosure of criminal activity**

If you are carrying out research where you may collect information with the potential for disclosure of serious criminal activity (e.g. research with young offenders/prisoners) **you should inform participants that confidentiality may not always be assured.** Please also ensure that you have discussed with the prison or institution an appropriate reporting procedure to follow if such information is disclosed**.**

1. **What will happen to the results of the study?**

Detail how the results will be made available to the participants and whether the results are to be published. If the results are to be published, detail how and where they will be accessible. Tell participants that they will not be identifiable from the results unless they have consented to identification.

1. **What will happen if I want to stop taking part?**

Participants should be informed that they can withdraw at any time, without explanation. Results up to the period of withdrawal may be used, if you are happy for this to be done. Otherwise you may request that they are destroyed and no further use is made of them. If results are anonymised, make clear that results may only be withdrawn prior to anonymization.

1. **Who can I contact if I have further questions?**

You should give the name, address, and contact telephone number of the **Principal Investigator.**

1. **OPTIONAL SECTION**

If the research involves vulnerable populations (e.g. women, human fetuses, neonates, prisoners, children, elderly, those with physical handicaps, mental disability, learning disabilities, economically disadvantaged, educationally disadvantaged, etc.) you will need to address how the participants will be protected and provided special considerations to ensure current regulatory frameworks are met.

**Duty of care to research participants**

Certain areas of research may have the potential for identifying a serious risk to the participant or to others, for example this might relate to the identification of a medical condition, financial concerns (e.g. severe debt), legal concerns, etc. **If you believe your research could identify such risks you should provide details in your information form of advice resources/details of any procedures that will be followed.**

For example:

1. in the event of discovering a medical risk, you may advise that information collected may be referred to an appropriate medical practitioner for examination
2. if you are studying consumer behaviour/spending behaviour you might include a section in the information form which gives the details of local/national agencies that participants may contact if they want further advice on debt.
3. if your research involves studying smoking or alcohol use, you could offer details of local/national agencies that might provide support, advise, and assistance to participants.