**PATIENT / PARTICIPANT INFORMATION SHEET TEMPLATE**

***Insert the study / project title here***

If your activity involves humans, participants must be clearly informed. A participant information sheet should contain the following information:

1. Logotype for the responsible organisation. More than one logotype may be adequate.
2. An easy to understand title.
3. The full title of the study / project, and the short title if relevant.
4. Short introduction explaining:
	* Short description of the topic. The information should not use terminology that may be difficult to understand.
	* The rationale for conducting this evaluation/quality activity.
	* What is expected to be achieved by doing the evaluation/activity. What questions can the evaluation/activity answer.
	* Describe who is organizing the evaluation/activity.
	* Describe who is funding this project (if any).
	* Mention a request for a decision to participate or not will be made, and, if the person choses to participate, a request to sign a consent form will be provided to the participant.
5. Clearly describe what participation involves. What will happen if the person decides to participate. Clearly describe demands, what is required of participants.
6. Describe any possible inconveniences and risks with participation.
7. Describe if participation results in possible benefits (medical, financial or others).
8. Describe that participation is voluntarily and that not participating **will not affect any routine treatment.**
9. Describe how collected information concerning participants will be treated regarding storage, privacy, confidentiality, and disclosure of information.
10. Information regarding if the person enrolls, he or she can later and at any time decide to withdraw their participation without being required to state any reason. If the patient withdraws participation - it will not influence the health care provided to the patient.
11. A statement that future information such as publications made in this project will be made available for those who wish to have it.
12. Outline that the FNQ HREC has reviewed and granted ethical approval for this project and include the generic contact details for the FNQ HREC.

Example wording:

*This study has been approved by the Far North Queensland Human Research Ethics Committee (Ref: HREC/xxxx/QCH/xxxxx). If you have any concerns regarding the ethical conduct of the study, please contact the HREC Coordinator on:*

*Phone: (07) 4226 5513*

*Email:* *FNQ\_HREC@health.qld.gov.au*

1. Include the name and contact details for the person/persons that can provide further information on the study / project or answer any questions from the patient/participant.

**PATIENT / PARTICIPANT CONSENT FORM TEMPLATE**

***Insert the study / project title here***

A consent form should be attached to the patient/participant information sheet as a separate document. If the person is less than 18 years old, a parent / guardian must also provide consent. The completed consent form should be kept as part of the project documents / filed in the patient’s/participant’s medical record. The patient should keep the information sheet and a copy of the consent form.

A consent form should contain the following information:

* Logotype for the responsible organisation. More than one logotype may be required.
* The full title of the study / project, and the short title if relevant.
* A declaration that the person may say no by not signing the consent form
* A declaration made by the Patient/Participant.

For example: *By signing this consent form I declare that I accept to participate and that I have understood the following:*

* + *The purpose, methods, risks, and inconveniences of the study as described in the information sheet.*
	+ *That I may not personally directly benefit from participating in the study.*
	+ *That my participation is voluntary, and I can withdraw at any time.*
	+ *I have been given information and the opportunity to ask questions.*
	+ *That the information specified in the information sheet concerning me may be stored in a research database for the purpose of this study.*
	+ *That any publication of the results will conceal my identity.*
	+ *I have been given a copy of the participant information sheet and consent form to keep.*
* The Participant’s name, signature, and date of signature.
* The name of a witness (if relevant), signature and date of signature.
* If relevant, also include the name, signature, and date of signature for an interpreter or parent/guardian.
* The Investigator’s name, signature, and date for signature. This should be signed by the investigator who is gaining the consent.