

GUIDELINES FOR INFORMED CONSENT

(SA GCP Guidelines 2006 : 1.2.8 pg 11; 3.5 pg 32)

Regulatory Framework :

Bill of Rights of the Constitution of South Africa
National Health Act

Guidance Documents :

Health Professions Council of SA
Ethics in Health Research: Principals, Structures and Processes
European Association of Palliative Care
MCC Guidelines : www.mccza.com
South African Good Clinical Practice Guidelines – 2006
Office of Human Research Protections : 21CFR50
CIOMS
ICH-GCP

Participant Information Leaflet :

Reference the document with the study title, version number and date.

The language of this document must be easily understood by the potential research participant.

To avoid role confusion please use the term 'participant' in research studies – 'patients' and 'subjects' are not acceptable terms.

The document needs to contain :

1. A greeting, introduce yourself and an invitation for the person to participate in the study.
2. An explanation to the potential participant that they can ask as many questions as they wish because it is important that they fully understand the study. Participants are entitled to discuss the study with their family and friends and are under no obligation to commit at this stage. For this purpose a copy of the Information to Participants document is given to the potential participant to take home.
3. A statement that the study involves research;
4. Who is paying for the research;
5. That the study has been approved by the HPCA Research Ethics Committee and it complies with the S A Good Clinical Practice Guidelines;
6. An explanation of the purposes of the research;
7. A description of the procedures to be followed;
8. The expected duration of the participant's commitment;
9. The approximate number of participants to be involved in the study.
10. A description of any reasonably foreseeable risks, discomforts or inconveniences;
11. A description of any benefits to the participant or others which may reasonably be expected from the research;
12. A disclosure of any appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
13. A statement describing how privacy and confidentiality of the participant's information will be maintained;
14. Any limits to confidentiality needs to be explained – who might have access to the data and under what circumstances;

15. That participation is totally voluntary, that they will still continue to receive the appropriate standard of care should they wish not to participate ;
16. That the participant is entitled to withdraw from the study at any time should they wish to do so and will still continue to receive the appropriate standard of care;
17. That the researcher may, under certain circumstances, decide to withdraw the participant from the study;
18. What procedures are in place for an orderly termination of participation by the participant;
19. Any significant new findings developed during the course of the research will be conveyed to the participant and they are entitled to decide whether they wish to continue in the study or not;
20. Explain how the researcher plans to disseminate the results of the research;
21. Participants to be informed how research documentation - tape recordings, video recordings, pictures taken, etc. may breach confidentiality and that these materials will be stored for 2 years following publication or 6 years without publication;
22. A separate consent form needs to be completed for the use of photographs, video recordings, and tape recording materials;
23. What, if any, compensation will be paid to the participant;
24. Contact details of the researcher in case there are any research related queries;
25. Contact details of the HPCA Research Ethics Committee for any human rights and ethics queries. (e-mail cborresen@iburst.co.za – telephone : 031 261 7868)

Participants need to be informed and permission requested for any video taping, tape recording or photographs that are required and a separate consent needs to be taken. These materials will need to be stored for 2 years if the research is published and for 6 years if not. An explanation on how the materials are to be stored will need to be explained together with an explanation of how breaches of confidentiality will be handled, should it occur.

Consent document (example) :

Study title, version number and date.

I confirm that I have been informed about the above study by

I have also received, read (or had explained to me), and understood the study as explained in the Participant Information Leaflet.

I understand that my personal details (any identifying data) will be kept strictly confidential.

I understand that I may, at any stage, withdraw my consent and participation in the study and will continue to receive the appropriate standard of care.

I have had sufficient opportunity to ask questions and am prepared to participate in the study.

Document to be signed, thumb-printed or marked and dated by :

- the participant;
- an independent witness;

For the person taking consent :

I have explained the above research protocol to

(Signature of person taking the consent)

(Date)

For illiterate participants :

I confirm that I have explained (or translated) the above study to and am confident that he/she understands what the study entails.

(Signature of the person who explained or translated)
(Date)