Guidelines for the drawing up of an *Informed Consent* Form for research involving human beings

Informed consent is an "agreement given by a person of legal age who is in full possession of their faculties" and who:

1) has received the necessary information about the study protocol;
2) has an adequate understanding of the information;
3) has considered the information and has reached a decision without having been coerced, influenced, cajoled or intimidated.

The drawing up of this document will require time, creativity and knowledge of the participant population. It is not merely a legal document; it is also a moral instrument and a process of communication between the researcher and the participant.

This form must respect the rights of any person participating in a study:

1) to have access to complete and comprehensible information
2) to participate on a voluntary basis
3) to receive an explanation of the costs/benefits arising from the research
4) to be in agreement with costs that he/she may have to bear
5) the existence of methods used to prevent/mitigate his/her discomfort and physical and mental suffering
6) to cease his/her participation at any time during the course of the research and with no negative consequences.

<u>Details to be included</u>:

- The project title;
- The names of the principal researcher and co-researchers;
- A description of the research: what will be done, why it will be done and how it will be done;
- A description of the subject's participation in the research, including experimental procedures;
- If the subject will be supplying a set of data/sample of biological products, indicate whether these will be destroyed or retained and how; if the latter, indicate how anonymity will be safeguarded;
- Information about the foreseeable risks/costs of participation and compensation in the event damages being caused;
- Information about the foreseeable benefits of participation; if there are no direct benefits for the participant, this should be indicated;
- Information about how the confidentiality of the verified data will be ensured;
- Indication of whom to contact in the event of problems or questions about the participant's rights;
- Indication of the voluntary nature of participation and the right to withdraw from the research at any time;
- A statement by the participant confirming that he/she has been informed of the conditions of his/her participation and understands and accepts them; in the case of subjects who are minors or who are not legally competent, provision should be made for consent to be given by the person legally responsible for them. In the case of subjects who do not know how to read or write, the researcher or his/her representative must read and explain the consent form to the participant, who will then "sign" the consent form with a fingerprint in the presence of a witness.