



## **Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research**

Strasbourg, 25.I.2005

### **Appendix – Information to be given to the ethics committee**

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Information on the following items shall be provided to the ethics committee, in so far as it is relevant for the research project:

#### **Description of the project**

- i the name of the principal researcher, qualifications and experience of researchers and, where appropriate, the clinically responsible person, and funding arrangements;
- ii the aim and justification for the research based on the latest state of scientific knowledge;
- iii methods and procedures envisaged, including statistical and other analytical techniques;
- iv a comprehensive summary of the research project in lay language;
- v a statement of previous and concurrent submissions of the research project for assessment or approval and the outcome of those submissions;

#### **Participants, consent and information**

- vi justification for involving human beings in the research project;
- vii the criteria for inclusion or exclusion of the categories of persons for participation in the research project and how those persons are to be selected and recruited;
- viii reasons for the use or the absence of control groups;
- ix a description of the nature and degree of foreseeable risks that may be incurred through participating in research;
- x the nature, extent and duration of the interventions to be carried out on the research participants, and details of any burden imposed by the research project;
- xi arrangements to monitor, evaluate and react to contingencies that may have consequences for the present or future health of research participants;
- xii the timing and details of information for those persons who would participate in the research project and the means proposed for provision of this information;

- xiii documentation intended to be used to seek consent or, in the case of persons not able to consent, authorisation for participation in the research project;
- xiv arrangements to ensure respect for the private life of those persons who would participate in research and ensure the confidentiality of personal data;
- xv arrangements foreseen for information which may be generated and be relevant to the present or future health of those persons who would participate in research and their family members;

**Other information**

- xvi details of all payments and rewards to be made in the context of the research project;
- xvii details of all circumstances that might lead to conflicts of interest that may affect the independent judgement of the researchers;
- xviii details of any foreseen potential further uses, including commercial uses, of the research results, data or biological materials;
- xix details of all other ethical issues, as perceived by the researcher;
- xx details of any insurance or indemnity to cover damage arising in the context of the research project.

The ethics committee may request additional information necessary for evaluation of the research project.