

THE DEVELOPMENT OF NUGO GUIDELINES ON BIOETHICS IN HUMAN NUTRIGENOMICS RESEARCH

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The European Nutrigenomics Organisation (NuGO) was established in 2004 to integrate and facilitate nutrigenomics research across Europe. The remit for NuGO Work Package Six (WP6) is to develop guidelines and standards for nutrigenomics studies in humans. Recognising the importance of ethical issues in this emerging area of science and the lack of appropriate bioethical guidelines, WP6 set the development of such guidelines as one of its primary objectives. To address the perceived needs of researchers in the field, this exercise focussed on four specific areas namely i) information and consenting prior to a nutrigenomics study, ii) the generation and use of genotype information, iii) the establishment and maintenance of biobanks, and iv) the exchange of samples and data. A thorough search of the available biomedical, bioethical, and legal literature was undertaken to identify publications with information relevant to one or more of the four specific areas of interest. In addition, an online questionnaire was applied requesting all NuGO scientists involved in human research to share their personal experiences and opinions regarding these four bioethical issues and the policies of local bioethics committees, and other regulatory bodies in respect of nutrigenomics studies. Furthermore, a workshop with a panel of experts in medical law, bioethics and philosophy was convened to discuss the draft guidelines. It was agreed that most of the international guidelines, recommendations and legislation regarding genetic information focus on monogenic disorders due to inherited mutations in highly-penetrant genes. The genetic information acquired during nutrigenomics research differs from this in various aspects. Nutrigenomics research rarely deals with genetic information that would determine unequivocally an individual's health status. In most cases, the genotypic information generated within nutrigenomics research projects represents influences that are often not greater than that of life style factors such as diet. In addition, nutrigenomics research generates and uses genetic information where the relevance for health outcomes is not yet clear.

The 21 guidelines developed in this exercise will be made available to the research community in 2006 using an interactive on-line tool. This tool will be designed to provide the appropriate guideline for the respective research situation supplied by examples, important documents, templates, links to other web pages, etc. Furthermore it will capture user comments which will be used to adapt the tool to the needs for information and guidance on bioethics for nutrigenomics researchers initially across Europe and with the potential for worldwide use.

The aim in development of these guidelines, as well as the on-line tool, is to provide a norm which will encourage the highest ethical standards in the rapidly developing science of human nutrigenomics.