

Author / Date: _____	ECRIN	Doc No: QP-NUTR-0001
Authorised By / Date: _____	NUTRITION	Date of issue:
Edition No. 00	Quality Policy	
<i>Reviewed By/Date:</i>		



EUROPEAN NUTRITION RESEARCH CENTRES QUALITY POLICY

Quality Policy Statement

The Nutrition Research Centres aspire to be centres of excellence as judged by the users of the service and the wider Nutrition research community.

The aim of the centres is to maintain quality management systems that not only meet the requirements of applicable national and international regulations and guidelines but also add value to the reputation of the Centres as locations where high quality, robust research is conducted.

Research activities are conducted according to the Declaration of Helsinki (2013), in accordance with Good Clinical Practice E6 (R1) version 4 as defined by the International Conference on Harmonisation (ICH), and with the applicable national and local regulatory requirements.

Research activities are conducted according to the approved, most recent version of the protocol and any relevant Standard Operating Procedures (SOPs) provided by the Sponsor of the research.

Research activities conducted in the centres can be selected for audit for Good Clinical Practice compliance and adherence to SOPs.

The centres ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor and comply with procedures for data recording/reporting, to permit monitoring, auditing and inspection and to retain the trial related essential documents.

The centres ensure and document that the electronic data processing system(s) conforms to established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation).

- Maintains SOPs for using these systems.
- Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e. maintain an audit trail, data trail, edit trail).
- Maintain a security system that prevents unauthorized access to the data.
- Maintain a list of the individuals who are authorized to make data
- Maintain adequate backup of the data.
- Safeguard the blinding

Author / Date: _____	ECRIN	Doc No: QP-NUTR-0001
Authorised By / Date: _____	NUTRITION	Date of issue:
Edition No. 00	Quality Policy	
<i>Reviewed By/Date:</i>		



EUROPEAN NUTRITION RESEARCH CENTRES QUALITY POLICY

In order to ensure the needs and requirements of the users are met, the Centres will:

- Integrate their procedures, processes and resources so that personnel are trained and understand the quality documentation.
- Set quality objectives and plans in order to implement this quality policy.
- Commit to the health, safety and welfare of all subjects, visitors and personnel in the Centres.
- Comply with relevant environmental legislation.
- Uphold professional values and commit to good professional practice and conduct.

The Nutrition Research Centres Management is committed to maintaining the quality system so that the requirements of Good Clinical Practice are met on an ongoing basis. Through its quality management system, the Centres aim at all times to ensure that the service is of a standard required to achieve maximum research benefit resulting in high quality research services, which is accessible, timely and comprehensive.

The Nutrition Research Centre is also committed to:

- Personnel recruitment, induction, training, development and retention at all levels so as to provide a full and effective service.
- The correct procurement and maintenance of equipment and other resources as are needed for the provision of the service.
- The handling of samples in such a way as to ensure the correct performance of testing.
- Testing procedures that will ensure the highest achievable quality of all tests performed.
- The reporting of test results in ways that are timely, confidential, accurate and clinically useful.
- The assessment of user satisfaction, internal and external audit, in addition to internal and external quality assurance assessment, in order to ensure continual quality improvement.

Signed (Management Team):

