Introduction

- The purpose of the Quality Policy QPNUTR0001 is to show the commitment of the management and quality teams of the centres to follow the relevant standards and to state the research centre's philosophy and policies toward satisfying standard requirements.
- The purpose of the Standard Operation Procedures (SOPs) is to ensure that the processes are performed under standardised conditions.

Methodology

The ECRIN WP6 Nutrition network of 73 nutrition centres was contacted for their SOPs. The procedures received from the centres were reviewed and a common procedure was established.

The SOPs were then reviewed by the WP6 expert group.

The finalised SOPs were then circulated to the Nutrition Network and the WP6 expert group for any closing comments.

The following documents were referenced in the relevant procedure:

European Nutrition Research Centres Quality Policy QPNUTR0001

- Declaration of Helsinki (2013)
- Good Clinical Practice E6 (R1) version 4 as defined by the International Conference on Harmonisation (ICH)
- National and local regulatory requirements

Blood Sample Collection Nutrition Centres SOPNUTR0001

- WHO guidelines on drawing blood: best practices in phlebotomy, 2010
- Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Clinical Laboratory Standards Institute, Approved Standard—Sixth Edition December, 2010
- UK Biobank Blood Sample Collection, Processing and Transport, Version 1.0, 2011
- BioSHaRE Blood Withdrawal, Version 1.0, 2012

Transport of Samples Nutrition Centres SOPNUTR0002

• WHO /CDS/EPR/2007. Guidance on regulations for the transport of infectious substances 2007.

- ADR: European Agreement concerning the international carriage of Dangerous goods by Road, entered into force on 29/01/1968, regularly amended and updated for entry into force on 1 January 2013, a revised consolidated version has been published as document ECE/TRANS/225, Vol. I and II ("ADR 2013").
- European regulation on blood and blood components: mother Directive 2002/98/EC of 27 January 2003 and daughter directives 2004/33/EC, 2005/61/EC and 2005/62/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.
- JORF French Official Journal No. 105 of 5 May 2002 Page 8703 Text No. 129 Decree of 24 April 2002 on the approval of the Regulation on best practices for transporting samples, and products derived from human blood samples.

Adipose Tissue Biopsy Nutrition Centres SOPNUTR0003

- SOP for adipose tissue needle Biopsy University of Leeds, human appetite research unit.
- SOP for adipose tissue needle Biopsy, Huddinge University Hospital 9/3 2001
- Mode opératoire : Biopsie de tissu adipeux A l'aiguille CRNH-RA-Version 001, CHLS Pierre Bénite- France

Measurement of body composition by DEXA Nutrition Centres SOPNUTR0004

- Mesure de la masse adipeuse totale Ostéodensitomètre Lunar iDXA ICANinvestigation.
- Mode Procedure for Dual Energy X-Ray Absorptiometry (DEXA) Scans Physiology Laboratories University of Nottingham Medical School
- SOP Measurement of body composition by DEXA Diogenes
- Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom
- Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation
- JORF French Official Journal Decision of 20 April 2005 laying down the procedures for quality control of densitometer devices using ionizing radiation

Measurement of body composition by IMPEDENCEMETRY Nutrition Centres SOPNUTR0005

- Bioimpedence SOP Physiology Laboratories University of Nottingham Medical School.
- Procédure d'utilisation de l'impédancemètre Bodystat Quadscan 4000- Unité d'Exploration en Nutrition Centre de Recherche en Nutrition Humaine CRNH Auvergne
- Impédancemètre Bodystat Quadscan 4000 Centre de Recherche en Nutrition Humaine CRNH Rhône-Alpes.

Muscle Tissue Biopsy Nutrition Centres SOPNUTR0006

- SOP Skeletal Muscle Biopsy University of Las Palmas de Gran Canaria, Institute of Biomedical Research. Luis Serra
- SOP Skeletal Muscle Biopsy A.Rivelles
- SOP Muscle Biopsy Technique for vastus lateralis
- Mode opératoire : Biopsie de tissu musculaire à l'aiguille CRNH-RA-Version 001, CHLS Pierre Bénite- France
- Mode opératoire : Biopsie de tissu musculaire à la pince CRNH-RA-Version 001, CHLS Pierre Bénite- France

Conclusion

- The procedures are considered templates that can be adapted as required by the centres.
- It is the responsibility of the management and quality teams in the centres to ensure that the procedures are adapted, accurate and followed.
- The procedures will be made available to the network on the ECRIN WP6 Nutrition website.
- Accreditation and certification of the Nutrition centres will be essential in order to certify the level of excellence of the centres and assist in the improvement of the processes.