National final qualifications for BROK®

After following the BROK® in the UMC, the investigator will have knowledge in the area of the subjects mentioned below and will be able to apply this within his own research.

The following are important points of interest:

a. The integrity of the investigator
b. Safety of the patient and reliability of the research data

Legislation and regulations, codes of conduct and other guidelines related to research involving human subjects in general

- Medical Research (Human Subjects) Act (WMO)
- Medical Treatment Contract Act (WGBO)
- Personal Data Protection Act (Wbp)
- European guidelines on Good Clinical Practice (2001/20/EG), Medical Aids (93/42/EG) and Active Implementable Medical Devices (90/385/EG)
- ICH-GCP (Good Clinical Practice) guideline (International Conference on Harmonisation of technical requirements for the Registration of Pharmaceuticals for Human Use)
- Declaration of Helsinki (World Medical Association)
- Instruction Manual Clinical research with medicinal products in the Netherlands (Ministry of Health, Welfare and Sport 2005)
- Code of Conduct for Health Research and Code of Conduct for Responsible Use (Federation of medical scientific associations)
- Scientific Integrity UMC
- Quality assurance of research involving human subjects (NFU)

Relevant institutions involved

- Central Committee on Research involving Human Subjects (CCMO)
- Medical Ethics committee (MEC)
- Ministry of Health, Welfare and Sport
- Medicines Evaluation Board (MEB)
- Health Care Inspectorate (IGZ)
- Dutch Data Protection Authority (DPA)
- DEKRA (formerly known as KEMA)
- Netherlands Institute for Accreditation in Healthcare (NIAZ)
- European Medicines Agency (EMA)
- Food and Drug Administration (FDA)

General project organisation and quality assurance

- Responsibilities and positions of the sponsor, investigator, research staff (e.g. research nurse)
- Investigator-initiated versus commercial research
- Risk classification of the research and its consequences
- Data management (Case Report Form (CRF), databases)
- Project management
- Monitoring / monitor requirements
- Budget and funding
- Filing (Trial Master File, Investigator File)
- Digitalisation and archiving
- Monocentre and multicentre study
- Insurance (study subjects and liability)
- Auditing
- Standard Operating Procedures (SOPs)
- Trial register and public accessibility in general
- Registration of personal data with the Dutch Data Protection Authority (DPA)
- Quality assurance of the institute (NIAZ)

Assessment

- Determining aspects that are governed/not governed by the WMO and aspects that need/need not be submitted for assessment.
- Study dossier
  - protocol (recruitment procedure, procedure for reporting adverse reactions (SAEs/ SUSARs), randomisation procedure, monitoring plan), study subjects information form and informed consent form, DSMB plan, study contract etc.
- Submission procedure to the MEC (ToetsingOnline) and Competent Authority
- Monocentre and Multicentre study (Guideline on External Assessment)
- Registering medicine studies with the European Union Drug Regulating
  - Authorities Clinical Trials (EudraCT)
- Progress report and final report

Pharmacy

- Definition of medicines study (IMP, non-IMP)
- Main aspects of Good Manufacturing Practice (GMP)
- Phases of medicines study
- Investigational Medicinal Product Dossier (IMPD) and Investigators Brochure (IB)
- Preparation (permit) and labelling
- Logistics of randomisation, blinding, de-blinding

Laboratory

- Main aspects of Good Laboratory Practice (GLP)
- Quality control and certification (ISO)
- Reference values
- Local logistics
- Shipment and storage of (body) material; labelling and encoding

Medical Devices

- Definition of Medical devices; risk classification
- Medical devices directives (93/42/EG and 90/385/EG)
- Main aspects of ISO standards, including ISO 14155 (Clinical investigation of medical devices for human objects)
- CE mark
- UMC internal procedure

Data Safety Monitoring Board (DSMB) / Safety committee

- When to set up
- DSMB charter
- Members of DSMB
- Types of contract (study contract, publication agreement etc.)
- Declaration of Confidentiality
- Insurances (study subject and liability)
- Intellectual property (valorisation, patents)

Methodology - basic principles

- Study design
- Objectives
- Methods
- Statistical analysis

Other subjects

- Biobank
- Research not governed by the WMO - aspects needing to be satisfied
- Ethics
- Integrity of the investigator (research code)
- Risk classification

Optional subjects within the BROK®

- Medical writing
- Medical Technology Assessment (MTA)
- Radiology - handling pictorial material

Utrecht, December 2012