Training and Examination Regulations (OER) for the Basic course on Regulations and Organisation for clinical investigators (BROK®)

1. Objective and definitions

Clinical investigators in the university medical centres (UMCs) who are involved in medical-scientific research that falls under the scope of the Medical Research Involving Human Subjects Act (WMO), Clinical Trials Regulation (CTR) and/or Medical Device Regulation (MDR) are obliged to take a Basic course on Regulations and Organisation for clinical investigators (BROK®) and successfully pass the concluding national exam.
The BROK® prepares investigators for their role in medical-scientific research, which safeguards the quality of research conducted in the UMCs. Obtaining the BROK® certificate confirms knowledge of the legislation in the field of medical-scientific research and guidelines like Good Clinical Practice (GCP) and ISO14155.

Definitions:

a. BROK®: Basic course on Regulations and Organisation for clinical investigators. The content of the BROK® is the property of the Netherlands Federation of UMCs (NFU). The content and the exit qualifications and test targets ('eind- en toetstermen') of the BROK® are evaluated periodically and adjusted if necessary by the BROK® committee. The exit qualifications and test targets set by the NFU can be found on the NFU website.

b. BROK® committee: NFU committee on which all UMCs, the secretary from the NFU Bureau and the Promovendi Netwerk Nederland (PNN) are represented. Other members include a representative of the examination agency (EMWO), a representative of the eBROK provider, and representatives of the hospitals that offer a centre-specific component for the BROK® course.

c. eBROK: BROK® course in e-learning form. The eBROK consists of an interactive e-learning course (basic modules and an in-depth module), a centre-specific meeting (CSB) and the BROK® exam. The interactive e-learning course and the BROK® exam are the same for all centres, while the centre-specific meeting is created for each centre individually based on the learning objectives.

d. WMO research: research that is subject to the Medical Research Involving Human Subjects Act (WMO).

e. Clinical investigator: scientific investigator who is responsible for and/or involved with the design, conduct and/or completion of medical-scientific research.

f. EMWO: Examenbureau Medische Wetenschappelijk Onderzoeker [medical-scientific researcher examination board] forms part of the eX:plain Foundation.

g. BROK® exam: a digital exam testing the knowledge acquired during the BROK® course that is done under supervision using computers.

h. Redactiecommissie (Editorial committee): committee set up by EMWO to set the content of the BROK® exam. It consists of at least seven representatives originating from the UMCs, CCMO, STZ, scientific associations, industry and EMWO.

i. BROK® certificate: a certificate standardised by the NFU that is awarded to those who have completed all mandatory parts of the eBROK course and successfully passed the BROK® exam.

j. Continuous learning process: after completion of the course and the exam, the course participant retains access to the online learning environment (if a subscription was purchased) to keep up to date with any changes in the law and relevant news and the latest knowledge.

k. Re-registration certificate: a certificate standardised by the NFU that is awarded to those who have completed the re-registration in the learning environment.

l. Candidates: people participating in the eBROK or the re-registration course.

m. BROK® registry: a registry maintained by the NFU of all those who have obtained a BROK® certificate.

2. Conducting exams

According to the agreement between the NFU and the eX:plain Foundation, the NFU has entrusted the conduct of the BROK® exam to the latter.

3. Obligation, certification, re-certification and registry

a. Obligation

The executive boards have made it mandatory for all clinical investigators setting up, conducting and/or completing research that falls under the scope of the WMO, CTR and/or MDR to be BROK®-certified.

The following applies to this obligation:
- The obligation concerns all investigators who conduct research activities on study subjects.
- The obligation applies not only to the principal investigator or the investigator submitting the METC application, but to all involved investigators, including heads of departments where the research takes place.
- The obligation applies also to researchers who do not have direct contact with patients, e.g. an investigator who writes the protocol or submits the METC application.
- The obligation applies to both doctors and those who are not physicians (e.g. pharmacists, psychologists, human movement scientists).

BROK®-certification is not mandatory for investigators in studies that are not subject to the WMO, but it is recommended. The eBROK contains a more in-depth module called ‘Non-WMO research’.

BROK® certification is ***not*** mandatory for:
- Students;
- Other research personnel, for example research nurses, study coordinators and data managers (if they are not an investigator);
- Statisticians, methodologists or other experts who are consulted;
- People who carry out activities in the context of standard care for patients participating in the study/trial;
- People who are involved in a single routine activity or treatment as part of the clinical trial, e.g. a lab determination or radiograph;

- People who conduct fundamental research in the laboratory.

The above-listed people must at least be aware of the WMO and Good Clinical Practice (WMO/GCP) if they carry out a delegated task in a clinical trial.
The executive board of an UMC decides how to deal with the obligations listed above.
People who do not fall under the described obligation can be admitted to the BROK® course, do the exam, obtain a certificate and become registered. The responsibility for supervising this rests with the involved department heads.

b. Certification

Candidates who have completed all mandatory parts of the eBROK course and successfully passed the BROK® exam are BROK®-certified. EMWO determines which candidates have passed the exam and who is BROK®-certified. The authorisation based on the BROK®-certification is valid for a period of 3 years. The registration can be extended by three years if the requirements for re-registration have been met before the BROK® registration has expired.

c. BROK® registry

EMWO together with NFU is responsible for the publication of the key data of the candidates who are certified/re-certified in the publicly accessible BROK® registry on the NFU website. Only those who are BROK®-certified are included in the BROK® registry. The certification history remains accessible. An objection can be lodged against open publication in the BROK® registry.

4. Objection & appeal

Any candidate who feels disadvantaged by some part of the exam can submit an objection to EMWO within 4 weeks of the publication of the result. If the outcome of this process is unsatisfactory, the candidate has the option to submit a written complaint to the Central Appeals Committee of the NFU ('NFU Centrale beroepscommissie') by e-mail addressed to nfu@nfu.nl. The Central Appeals Committee was established by the NFU board and consists of the chair of the BROK® committee, a recently certified investigator and an independent outsider. The Central Appeals Committee can be supported by one or more advisors and/or an official secretary. If one of the members is directly involved in the objection, they recuse themselves and deputise NFU as their replacement. The judgement of the Central Appeals Committee is binding for the applicant and the EMWO.

5. Conflicts

If conflicts arise regarding this OER, which are not objections as specified under article 4, the parties can to turn to the Central Appeals Committee if they wish, which can issue a binding judgement.

6. Implementation

By approving this document in the context of NFU, the UMCs commit to implement this OER in their own institution. The current version of the OER came into effect from April 2nd 2022.

7. Fraud

If fraud or other infringement of the valid examination protocol is confirmed, the result of the exam is declared invalid. In addition, participation in the exam can be denied for a maximum of 2 years.

8. OER evaluation

The NFU BROK® committee evaluates this OER at least every 2 years and revises it as necessary.

Utrecht, April 2022