BROK Training and Examination Regulations OER eBROK 2025

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), Medical Device Regulation (MDR) and /or the InVitro Diagnostics Regulation (IVDR) are obliged to take and successfully pass the Basic course on Regulations and Organisation for clinical investigators (BROK®).
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.

b. BROK® committee: NFU committee on which all UMCs and the secretary from the NFU are represented. Other members can be included where relevant.

c. eBROK: BROK® course in e-learning form. The eBROK consists of interactive e-learning (basic modules and in-depth modules) and a centre-specific meeting (CSB). The interactive e-learning course is 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. BROK® certificate: a certificate standardised by the NFU that is awarded to those who have completed all mandatory parts of the eBROK course.

g. After completing the basic course and at least one advanced module, the participant progresses to a re-registration tool that continuously keeps their knowledge up to date through adaptive learning.

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

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

j. BROK® registry: a public registry of all those who have obtained a BROK® certificate.

2. 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, MDR and/or IVDR 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 project proposal, 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 it.
- 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 strongly 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 have demonstrable knowledge 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 may still be admitted to the BROK® course. The responsibility for supervising this rests with the involved department heads.

b. Certification

Candidates who have completed all mandatory parts of the eBROK course are BROK®-certified. The authorisation based on the BROK®-certification is valid for a period of 1 year. The registration can be extended by a year if the requirements for continuous learning have been met before the BROK® registration has expired.

A certificate obtained in the 'old' environment remains valid for three years.

c. BROK® registry

GCP Central 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.

3. Objection & appeal

Complaints can be submitted to the BROK® committee via an email to the BROK® coordinator of the complainant's institution. If the complainant is not affiliated with one of these institutions, they may choose any BROK® coordinator to submit their complaint.
Contact details of the BROK® coordinators are available here.
Complaints are always handled confidentially.

When submitting a complaint, the complainant must provide the following information:
- Name and contact details of the complainant.
- A clear description of the complaint.
- Date and any relevant documents or evidence.

The complainant will receive an acknowledgment of receipt within 10 working days.
Within 20 working days after receiving the complaint, the complainant will receive a written response with a proposed resolution. If the complaint cannot be resolved within this timeframe, the complainant will be informed with an explanation and a new deadline.

If the complainant is not satisfied with the proposed resolution, they may submit a written appeal to the NFU at nfu@nfu.nl within 10 working days after receiving the response. The NFU will then assemble an independent appeals committee consisting of individuals who were not involved in the initial complaint assessment, including a recently certified researcher and an independent external party. The appeals committee may be assisted by one or more advisors and/or an official secretary.

4. Conflicts

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

5. 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 01 January 2025

6. Fraud

If fraud or other infringement is confirmed, the eBROK certificate will be declared invalid. In addition, participation in the eBROK® course can be denied for a maximum of 2 years.

7. OER evaluation

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

Utrecht, January 2025
