

AGRBM regulations on further education and training

Reproductive medicine deals with the medical treatment of involuntary childlessness. Applied human reproductive biology is the methodical complement to reproductive medicine in fertility treatment. Within reproductive medical procedures, it deals in equal parts with both the diagnosis and treatment of involuntary childlessness and contributes equally to the provision of services in IVF centres.

The differing aspects of reproductive biology require wide-ranging specialist knowledge in the fields of: germ cell development and gamete interaction, hormonal control of gametogenesis, implantation and pregnancy, human embryology, genetics and immunology. Scientific training also imparts the skills required for the evaluation, selection and implementation of new laboratory methods that are subject to rapid developments within assisted reproduction. Due to the dynamic development in reproductive biology, this field should be represented in IVF centres by an expert with proven qualifications in reproductive biology. The professional title of "Reproductive Biologist (AGRBM)" will be used otherwise in a uniform and neutral manner for "Female Reproductive Biologist (AGRBM)" and "Male Reproductive Biologist (AGRBM)". The same applies to the titles of candidates, scientists, etc.

Biologists and scientists from related disciplines are particularly qualified for tasks in Assisted Reproduction laboratories after obtaining a university degree in a relevant field. On the basis of this, they can acquire the additional expertise necessary for meeting the specific requirements of reproductive biology. They will be referred to below otherwise in short as "reproductive biologists".

A quality management system (QM) is now required in any medical facility. The specific quality assurance measures in reproductive biology laboratories require a high level of QM expertise in addition to an understanding of the methods. The technical qualification of the employees in the "processing-related" field (ART laboratory) is of particular relevance with regard to the implementation of the "EU Directive 2004/23/EG on setting the standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells", with its two technical additions – in the form of the Tissue Act of 20 July 2007 and the corresponding amendments in the German Ordinance for the Production of Medicinal Products and Active Substances (AMWHV).

With the introduction of the professional certification within "human reproductive biology" (Appendix 1), the German Society of Human Reproductive Biology (AGRBM) has documented that qualified individuals can independently select, carry out and assess methods of reproductive biology and interpret the results scientifically.

Compliance with the requirements stipulated in this further education regulation is verified by the German Society of Human Reproductive Biology (AGRBM) or its commission on further education and training which is responsible for the awarding of the professional title of "Reproductive Biologist (AGRBM)". After successful completion of the final examination, professional recognition is granted with the presentation of the certificate. The conferred professional title is proof of the acquired expertise.

Due to the particular sensitivity of this field, state recognition for "Human Reproductive Biology" is sought by the competent supervisory authorities.

The AGRBM has developed an additional further education regulation (Appendix II) in order to take into account the scientific development in the field of reproductive biology. It is mandatory for the heads of laboratories to participate in further education sessions, but they are also open to all reproductive biologists. Furthermore, candidates for professional recognition in "Human Reproductive Biology" use the relevant sessions to expand their training around the scientific principles of reproductive biology.

1. Definitions of terms

a) **Professional recognition in "Human Reproductive Biology"**: the completion of the activities given in the list of requirements which are shown in Appendix I, Item 2, is the prerequisite for admission to the examination for the obtaining of the professional recognition. The proof of the requirements set out in the continuing education regulation as well as the successful completion of the examination entitles an individual to the title of "Reproductive Biologist (AGRBM)" and is considered as confirmation of the professional competence and a prerequisite for an application as head of a laboratory head to the appropriate board of physicians.

b) **Further education**: is the achievement of the professional recognition in "Human Reproductive Biology" based on the specifications of the AGRBM.

c) **Training**: refers to continual attendance of technical, scientific and practice-oriented sessions with the goal of expanding and updating knowledge on reproductive biology (Appendix II).

d) **Laboratory for Assisted Reproductive Techniques (ART laboratory)**: an area of a reproductive medicine facility where all the relevant measures are undertaken using gametes and pre-implantation embryos as part of fertility treatment.

e) **Position of the Head of a Laboratory**: Each reproductive biology laboratory must employ at least one reproductive biologist who takes up the position of the Head of Laboratory in accordance with the admission regulations of the individual federal German states. This requires regular participation in further education activities. He or she must ensure that all the employees of the laboratory have received information on the further education sessions. The tasks of a laboratory head include the induction and supervision of laboratory employees, drawing up and monitoring of quality management actions and the establishment of new laboratory methods.

f) **Supervisor:** An external supervisor monitors the education of a candidate for professional recognition in "Human Reproductive Biology". He or she must have professional recognition in "Human Reproductive Biology" and at least 6 years of professional experience or, alternatively, must have the ESHRE qualification as "Senior Clinical Embryologist". Furthermore, he or she must continue to fulfil the further education requirements as defined in this FWB regulation.

g) **Examination board:** The members of the examination board are appointed by the commission on further education and training and the Managing Committee for a period of four years. Its members must meet the requirements imposed on the supervisors. Each final examination is conducted by two members of the examination board.

2. Objectives of the regulations on further education and training

The AGRBM considers it as its duty to ensure a consistently high level of work in ART laboratories at a federal German level. The professional recognition in "Human Reproductive Biology" therefore has the objective of setting minimum standards for the quality of the work and the level of training of the academic employees and of thus making a contribution towards quality assurance in medical care. Specific quality criteria must be met even for training new laboratory employees.

A distinction is made between further education in accordance with a listing of requirements (training regulation, Appendix I) and further education for reproductive biologists (further education regulation, Appendix II). Efficient and constant further education should enable reproductive biologists to create new state-of-the-art techniques in their own facility, to select appropriate methods and techniques in the laboratory and, where necessary, to advise patients in a competent manner.

The administration regulations of the regional board of physicians should establish that responsible reproductive biologists must meet the requirements set out in point 1.a. Furthermore, a laboratory head must be named from this group of people as set out in 1.e.

3. Commission on further education and training (FWB commission)

The FWB commission consists of a Managing Committee member and four members decided by the AGRBM assembly by means of a vote. The candidates must be recruited from among the supervisors. They serve for a period of four years; all the members of the FWB commission have equal rights. Decisions are taken by a simple majority. The FWB commission names a head and a deputy head from among its members.

The following tasks are the responsibility of the FWB commission:

a) The granting professional recognition in "Human Reproductive Biology" after successful completion of the examination (see Appendix I).

- Monitoring compliance with the admission requirements for the final examination for the obtaining of professional recognition in "Human Reproductive Biology". Once the candidate's performance in accordance with the listing of further education requirements is verified, the commission informs the candidate of an examination date as well as the name of the examiners. The admission requirements for the examination are specified in the training regulation. Compliance with these requirements is certified by the medical head of the reproductive medicine facility and the supervisor named in the application and submitted in writing to the FWB commission.
- A written notice on successful completion of the further education is issued on the basis of the decision of the examiners which is documented in the transcripts of the final examination.
- A decision is taken on admission for the examination for professional recognition in "Human Reproductive Biology" in individual cases where the prerequisites are unclear (for example, study courses abroad; recognition of work which may be attributed to the reproductive biologist at the time of admission).
- Decision in cases of hardship (for example: illness, parental leave, etc.)

b) Assignment of supervisors for the assisting of candidates for professional recognition

c) Tracking of compliance with the further education requirements

- Regular review of further education for laboratory heads with certificates of participation.
- Checking of the certificates received for further education sessions for recognition in accordance with the listing of further education requirements and, where necessary, the taking of an individual decision on the recognition.
- Issuing of the certificate for compliance with continuing education requirements in accordance with the listing of further education requirements (every two years).

The FWB commission is obliged to report to the Managing Committee. It submits applications, transcripts of the final examinations or certificates for professional recognition and further education to the Managing Committee for inspection. The AGRBM Managing Committee has a power of veto on the decisions taken by the FWB commission. In the case of a veto by the Managing Committee, the application is decided by the full assembly. The Managing Committee, the members of the FWB commission and the examination board are obliged to confidentially handle data specifically relating to a person and a centre.

4. Entry into force

The FWB regulation of the AGRBM, including the training regulation (Appendix I) and the further education regulation (Appendix II), has been in force since 1 March 2008. It replaces the first version of the FWB regulation from 14 May 2004 ("Concept for additional qualification of reproductive biologist"). The current version detailed here was adopted on 17 April 2015 during the general assembly in Dusseldorf and replaces all earlier versions.

Additions and amendments to the FWB regulation are carried out by means of a vote during the general assembly. The establishment of new techniques as routine methods as well as new theoretical focus areas are provided in the updated listing of further education requirements. The methods and focus areas in question can be suggested by any member of the AGRBM. Agreement on inclusion in the listing of further education requirements is carried out during the general assembly.