

Rules and Regulations for the Register of Biostatisticians

Preamble

The Register of Biostatisticians was installed by the Board of the Vereniging voor Statistiek en Operations Research (VVSOR), in cooperation with BMS-ANed, in 1999. The objective is to provide registration and accreditation of biostatisticians working in industry and academia, both in research, education and consultation, who have the required education and practical experience to take personal responsibility for their professional activities as a biostatistician.

Inclusion in the register of BMS-ANed guarantees that a person, in the opinion of the community of professional statisticians in the Netherlands, has sufficient theoretical knowledge and practical experience to function independently as a biostatistician. Registration is important because the educational background of biostatisticians in the Netherlands is very diverse and the title 'statistician' is not protected by law, which can make it difficult to judge whether people who call themselves biostatisticians are competent and sufficiently experienced to do a specific job. The minimum requirements that have been established for registration are that the person has successfully completed a master's degree with a strong statistical and/or methodological focus followed by at least a few years of professional experience to become a fully qualified biostatistician. Registered biostatisticians are expected to possess the required expertise to act as statisticians in boards and committees, including institutional review boards, data safety monitoring boards (DSMBs) and grant review committees.

The procedures and more detailed requirements for registration are described in this document and the application form.

1 General

BMS-ANed is responsible for the registration of biostatisticians and appoints the Board for Registration of Biostatisticians (hereafter BRB). Members of the BRB are appointed for a term of six years with the possibility of reappointment. The maximum term is twelve years.

2 Register

Registered biostatisticians are entered into the Register of Biostatisticians. This Register is kept by and is accessible to members of the BRB. In case of an appeal (as described in Article 9), members of the board of BMS-ANed also have access to relevant information in the Register. In the Register, the following information is entered at time of registration:

- personal details (name, email address, year of birth);
- date of registration.

Moreover, the following information is kept on file for reference by the BRB:

- application form
- documents submitted by the applicant to prove their experience and level of education
- the written considerations of the BRB
- permissions given for publication of personal details on BMS-ANed website
- if applicable, date of warning or reprimand, with the pertaining considerations.

Registered biostatisticians should inform the secretary of the BRB of any changes in their contact details. The secretary of the BRB may also contact the registered biostatisticians to ask for confirmation of their contact details. In case it is apparent that the registered biostatistician has passed away or if they indicate that they no longer wish to be included in the Register, the biostatistician will be removed from the Register and their personal data will be deleted. The person's name and date of start and end of registration may be kept on file for biostatisticians who have been removed from the Register. Furthermore, if the registered biostatistician does not respond to a request for confirmation of their contact details (also not after a reminder) or appears to be untraceable, the BRB may decide to

remove the biostatistician from the Register.

Registered biostatisticians will be asked for permission to have their name and date of registration included in a public extract of the Register that will be published on the BMS-ANed website. The BRB will provide newly registered biostatisticians with a digital certificate as proof of registration. If necessary, and only after a request of a registered biostatistician, the secretary of the BRB shall confirm to an external party that the biostatistician is indeed included in the Register. The members of the BRB and the board of BMS-ANed are obliged to observe secrecy regarding all information that has become known as part of the registration process.

3 Duties of the Board for Registration of Biostatisticians

The duties of the BRB are:

- judging and processing applications for registration, and registration of approved applications;
- keeping the Register and the related files;
- ensuring the information in the Register is up-to-date;
- judging possibly unprofessional conduct and, as a consequence, possibly removing the individual concerned from the Register, after a complaint has been filed (see Section 8);
- providing registered biostatisticians with a proof of registration;
- submitting an annual report to the board of BMS-ANed.

4 Composition of the Board for Registration of Biostatisticians

The BRB shall consist of three or four members:

- at least two professors or associate/assistant professors in statistics for life sciences;
- at least one registered biostatistician from a non-academic institution.

The members shall choose from their midst a president and a secretary.

5 Application fee

The board of BMS-ANed shall establish a fee, to be paid to BMS-ANed, for the application procedure, irrespective of registration. The amount of this fee may be lower for applicants who are current members of VVSOR and/or BMS-ANed.

6 Application procedure

Applications for registration should be addressed to the secretary of the BRB. The application must include proof of the relevant education and a curriculum vitae or extended report on the relevant experience. Within six weeks after receiving the application, the secretary of the BRB shall send an acknowledgement of receipt and the related invoice. Within three months after receipt of the application and after payment of the fee has been received, the BRB shall send a reply by email containing either its decision or the reasons for delaying the decision. A decision may be delayed once for a maximum period of three months. The BRB may contact the applicant to request additional information or clarification in order to make a decision.

Whenever possible the decision of the BRB should be unanimous. In case of disagreement, support of a strict majority of the members of the BRB is required for acceptance of the application. In case of acceptance, an electronic certificate will be sent to the applicant by email to serve as proof of registration. If the application for registration is denied, the reasons for denial shall be stated. The applicant may submit an appeal within three months' time (see Article 8). The board of BMS-ANed shall inform the applicant about the decision of an appeal within six months' time after receipt.

7 Requirements for registration

In order to be eligible for registration, applicants must meet the following requirements:

- A completed master's degree with at least 60 ECTS (one ECTS equals 28 hours of study time) in statistics, probability theory and methodology at a satisfactory level, or the equivalent thereof.

- At least five years of practical experience at an appropriate level in applying biostatistical methods to designing, analysing and reporting scientific research in the field of life sciences, with at least two years of experience with personal responsibility for the biostatistical work. A completed PhD counts as two years of experience.
- Being employed and/or living in the Netherlands at the time of filing the application.
- Two referees must vouch for the applicant's work, professional experience and training covering at least three of the five most recent years with their signature. At least one referee should be or have been in a position of seniority regarding the applicant in the covered period, unless the applicant was in a senior role for the period under consideration.

Individuals not meeting the degree requirement as stated above, who have ten or more years of practical experience at an appropriate level are equally eligible for registration, provided that they can acceptably substantiate that their knowledge of statistical theory and methods is comparable to the requirements stated above.

The BRB shall take all relevant forms of practical experience into consideration. The following list is an indication of the forms of experience that shall be considered, without being exhaustive:

- conducting and reporting of statistical data analyses;
- involvement in designing research, and responsibility for the statistical aspects of this;
- activities in statistical consultation;
- research in the field of biostatistical methods;
- leading a (bio)statistics group;
- teaching biostatistical methods and applications.

Referees who vouch for the applicant's work should preferably be registered biostatisticians themselves. It is however anticipated that this is not always possible and in such cases non-registered statisticians may vouch for the applicant's experience. If no referees can be found, e.g. because the applicant works independently, then additional evidence must be submitted, such as testimonials, publications and/or consultation reports for consideration by the BRB. At the discretion of the BRB, a certification as

biostatistician in another country may also be accepted as proof of competence. In case of doubt regarding the experience of the applicant, the BRB may choose a third referee in consultation with the applicant, and ask the third referee to vouch for the applicant's work.

8 Decisions and measures which the BRB may take

The BRB shall have the authority to decide that:

- an applicant shall be registered as a biostatistician;
- an applicant shall not be registered;
- a registered biostatistician shall be removed from the Register for a certain period or indefinitely, for motivated reasons such as proven unprofessional conduct.

Complaints concerning supposed unprofessional conduct may be submitted to the Secretary of the BRB. Unprofessional conduct is taken to mean conduct different from that of a skilled biostatistician acting reasonably under the same circumstances.

9 Appeal

Following a decision by the BRB not to register an applicant or to remove a registered biostatistician, the person concerned may lodge an appeal against that decision within three months from the decision date. Appeals should be submitted in writing to the secretary of the board of BMS-ANed. The appeal should include a specification of the reasons for the appeal and is preferably accompanied by supporting evidence. The possibility to lodge an appeal against a decision of the BRB shall expire when three months have passed from the date of the decision.

The appeal will be handled and decided upon by the board of BMS-ANed. Any member of the BRB who is also a board member of BMS-ANed will not be involved in handling the appeal. The appellant shall pay a fixed fee to BMS-ANed to handle the appeal. The amount of this fee is equal to the registration fee as described in Article 5. If BMS-ANed has not received the fee for appeal within 14 days after receipt of the written appeal, the board of BMS-ANed shall

declare the appeal inadmissible. If the appeal is granted, the fee for the appeal will be refunded.

After receiving the appeal, the secretary of the BMS-ANed shall send a copy of the appeal to the BRB without delay. The BRB shall submit a written defense to the secretary of BMS-ANed and the appellant within six weeks after receipt of the appeal. The appellant will be provided the opportunity to respond to the BRB's response in writing. The board of BMS-ANed shall offer both parties (that is, the appellant and the BRB) the opportunity to give a verbal explanation of their points of view during a session, unless parties waive this right. Written documents to which parties wish to refer must have been received by the secretary of BMS-ANed at least 7 days before the session. The president of the board of BMS-ANed shall preside over the session.

After this session has taken place, the board of BMS-ANed shall decide upon the appeal. The verdict should follow Dutch law and shall take into consideration the standards which are usually set in the field of expertise concerned. The board shall decide with a majority of votes. The verdict shall contain:

- the name of the appellant;
- a summary of the procedure;
- a summary of the parties' points of view;
- the considerations;
- the actual verdict.

Copies of the verdict, signed by the president and the secretary of BMS-ANed, shall be sent to the appellant and the BRB. The verdict shall be binding to both parties and no higher appeal shall be possible.

Parties may choose to be assisted by a lawyer or other legal advisor during the appeal procedure. Cases which have been brought before the board of BMS-ANed may not be brought before court, barring cases in which the appellant deems a provisional judgement necessary. The board of BMS-ANed, the BRB and their members shall not be liable for any action or omission in or connected to applying these regulations. In cases for which these regulations do not provide, the board of BMS-ANed shall decide.

Approved by the Annual Meeting of the Biometric Section on May 26, 1999, and by the Board of the VVS in its meeting of October 13, 1999. Amended version approved by the General Assembly of BMS-ANed on June 19, 2025.