

# Rules and Regulations for the Registration of Biostatisticians

## Preamble

Employers, government institutions and society at large increasingly make demands on biostatisticians who design and analyse Life Sciences research. The international Guideline for Good Clinical Practice, for instance, states that pharmaceutical research should involve qualified biostatisticians. Biostatisticians working in this field are often asked to prove that they are qualified. According to the Dutch law governing medical research on human subjects (Wet medisch-wetenschappelijk onderzoek met mensen), medical research involving human subjects must be approved by a medical-ethical examination board, which must include an expert on research methodology. The requirements regarding this expert mention a biostatistician with proven experience in medical research on humans.

Ever higher demands are also made on the statisticians involved in tests on animals and in agricultural research in general. In studies regarding the health value and safety of food and responsible development of the natural environment, the importance of statistics is increasing strongly, extending from genetics to complex questions of structuring our environment. This was recently emphasized in discussions on the dependability of complex models. Biostatistical input of recognized quality is needed here.

Laypersons, like many employers are, find it difficult to judge whether individuals who call themselves biostatisticians are sufficiently competent and experienced for a certain job. There is no specific training for biostatisticians in the Netherlands. There are some institutions where one can obtain a degree in statistics, but by far the largest number of working (bio-)statisticians has a different background. This situation is expected to last for the foreseeable future.

Against this background, the occupational group of biostatisticians increasingly feels the need for some form of registration or certification. The Dutch Society for Statistics and Operations Research (VVS) for this reason has decided to set up a register of biostatisticians. This register guarantees that a biostatistician in the opinion of the occupational group of statisticians in the Netherlands as represented by the VVS has sufficient theoretical knowledge and professional experience to be able to function as an independent biostatistician. It is hoped that the register will lead to a higher profile and a clearer outline of the occupational group (for its members benefit as well as for that of educational institutions, potential employers, government and regulating bodies), and to an adequate image in society. In establishing the registration, the VVS follows the example of countries such as the UK, New Zealand and Canada where a register of statisticians exists already and Germany, which has a register of biostatisticians. Registers are being set up in other countries as well.

In establishing registration requirements, we have been guided by the principle that individuals with a Masters degree with a strong statistical and/or methodological component, as well as hold-

ers of the VVS Statisticians Certificate, should have sufficient basic knowledge of statistics theory to be able to develop into fully skilled biostatisticians after some years of experience.

A combination of theoretical education and relevant practical experience which is extended and demonstrable is required for registration. We have thus chosen a form of registration very similar to the existing registration as a Chartered Statistician in the UK, which sums up the requirements as an appropriate academic degree in statistics or a subject with a substantial coverage of statistical methods and theory, plus five years practical experience in applying statistics.

## Rules and regulations

### 1 General

The Netherlands Society for Statistics and Operations Research (Vereniging voor Statistiek en Operationele Research, hereafter VVS) is responsible for the registration of biostatisticians. The VVS appoints the Board for Registration of Biostatisticians (hereafter BRB) on the recommendation of the board of the Biometric Section (hereafter BMS) of the VVS. Members of the BRB are appointed for a term of six years. Reappointment is possible. The Board of the VVS cannot discharge members of the BRB during their term, unless the Board of the VVS finds them wanting in the fulfillment of their duties.

### 2 Register

Registered biostatisticians are entered into the Register of Biostatisticians. This Register is kept by and is accessible to members of the BRB. Members of the Board of Appeal (BA, see Articles 7-9) also have access to the Register. In the Register, at least the following information is entered:

- personal details (name, email-address, year of birth);
- affiliation at the time of registration;
- date of registration;
- if applicable, date of removal from the Register.

Moreover, at least the following information is kept on file for reference by the BRB and BA:

- application form
- relevant education (with proof);
- relevant experience (with proof);
- the written considerations of the BRB and (if applicable) BA;
- if applicable, date of warning or reprimand, with the pertaining considerations.

The members of both Boards are obliged to observe secrecy regarding all information on file. If inquiries are made concerning the registration of a specifically named person, the Secretary of the BRB shall indicate whether or not that person is registered.

An extract from the Register shall regularly be made public on the VVS Website, indicating at least name, affiliation and date of registration whereas any individual confidentiality request will be taken into account.

### **3 Duties of the Board for Registration of Biostatisticians**

- The duties of the Board for Registration of Biostatisticians shall be:
- judging and processing applications for registration, and registration of approved applications;
- keeping the register and the related files;
- judging possibly unprofessional conduct (see Article 7) and, as a consequence, possibly removing the individual concerned from the Register;
- processing inquiries after the registration of specifically named persons;
- submitting an annual report to the Boards of the VVS and of the BMS.

### **4 Constitution of the Board for Registration of Biostatisticians**

The Board shall consist of four Members:

- two professors or senior lecturers in Statistics for Life Sciences;
- two biostatisticians from non-academic institutions who are held in high esteem, preferably Heads of Departments of Statistics for Life Sciences.

The Members shall choose from their midst a President and a Secretary. The Board may choose to be supported by an external secretary.

### **5 Financial**

The Board of the VVS shall establish a fee for the application procedure, to be paid by the applicant.

### **6 Registration procedure**

Applications for registration shall be addressed to the Secretary of the BRB. They must include proof of the relevant education and an extended report on the relevant experience. Two referees must vouch for the applicants experience with their signature. The referees must be biostatisticians who already are registered and who have first-hand knowledge of the applicants work. If no referees can be found, e.g. because the applicant works on his or her own, then additional evidence must be submitted, such as testimonials, publications and/or consultation reports for consideration by BRB. Acceptability of foreign referees is at the discretion of the BRB and will at least require for being accredited/registered if such a scheme exists in their home country.

Within six weeks after receiving the application, the Secretary of the BRB shall send an acknowledgement of receipt and the related invoice. Within four months after receipt of the application and as soon as payment of the fee has been received, the BRB shall send a written reply containing either its decision or the reasons for delaying the decision and a time limit. Acceptation of applicants requires the support of at least three members of the BRB. If registration is denied, the reasons for denial shall be stated. The applicant may enter an appeal within three months time (see Article 8). The appeal shall be dealt with in six months time after receipt at the latest.

## 7 Requirements for registration

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

- a Masters degree from a Dutch university or a foreign equivalent thereof or a VVS Statisticians Certificate. This education must include at least 60 units of European Credits (one unit equals 28 hours of studying time) in statistics/calculation of probability/methodology of a satisfactory level, or the equivalent thereof (f.i. 42 units of studiepunten (one unit equal to 40 hours of studying time), at the discretion of the BRB);
- 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 - of these five, at least two years with personal responsibility for the biostatistical work.

Individuals not meeting the degree requirement as stated above, who have ten or more years of practical experience on 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 statistics group;
- teaching geared toward practical use, of biostatistical methods and their applications.

Applicants who do not (as yet) meet the experience requirements may request the BRB to judge only if they meet the requirements as to education. The BRB shall give a definite answer in writing.

## 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 definitively, on account of unprofessional conduct;
- a registered biostatistician shall be given a warning on account of unprofessional conduct;
- a registered biostatistician shall be given a reprimand on account of unprofessional conduct.
- Unprofessional conduct is taken to mean conduct different from that of a skilled biostatistician acting reasonably under the same circumstances. Complaints concerning supposed unprofessional conduct may be submitted to the Secretary of the BRB.

## **9 Appeal**

Following a decision by the BRB not to register an applicant or to remove, warn or reprimand a registered biostatistician, the person concerned may lodge an appeal to the Board of Appeal within three months from the decisions date. The appeal procedure is governed by the Regulations for Appeal. The appellant shall owe a fixed fee for the appeal procedure, the sum of which shall be established by the Board of the VVS.

## **10 Board of Appeal**

The Board of Appeal shall consist of a President and four Members. The President, the Secretary and one Member shall be appointed by the Board of the VVS, one Member of the Board of Appeal shall be designated by the BRB, and one by the appellant. The President shall decide where the Board of Appeal resides.

## **11 Termination of registration**

Active registrations will become terminated in case of death or if the registree informs the BRB that (s)he wants to end registration for personal reasons (e.g. retirement, switching to another discipline, not being active as statistician anymore, etc.).

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