

European Board of Medical Genetics

Standard Operational Procedure of the Branch of Clinical Laboratory Genetics (B-CLG)

I. General

The EBMG Branch of Clinical Laboratory Geneticists has developed a set of standards and a curriculum for Clinical Laboratory Geneticists (CLGs) undertaking analysis of genetic material and providing technical and clinical interpretation of the results. These standards reflect consensus amongst experts in this field from a wide range of European countries and apply to professionals trained in either clinical science or medicine who are working in clinical genetic laboratory settings. Two corresponding sister-branches under the roof of the EBMG exist for MDs who are specialized as Medical Geneticists and for Genetic Nurses & Genetics Counsellors. Although there is significant overlap with the standards and curricula of the sister branches, the CLG recognition has additional and/ or unique requirements. To apply for CLG recognition the candidate must cover the full spectrum of clinical laboratory diagnosis, familiarity with laboratory techniques and interpretation of data in a depth, distinct from that required by sister branches.

This branch of Clinical Laboratory Genetics (B-CLG) is a representation of CLGs, i.e. primarily non-MDs with natural science / biology as background, who practice, supervise and lead lab-work related to clinical genetic diagnostics (including all sub-specialisations, such as: cytogenetics and molecular cytogenetics in (pre- and post-natal, tumour); molecular genetics; biochemical genetics). In addition, CLGs are involved in writing and signing lab-reports; MDs can also seek recognition as CLG if their primary work activities correspond to this description. MDs involved in similar activities who also see patients must seek affiliation with the branch of medical geneticists, not the CLG branch.

This EBMG branch (B-CLG) main purpose is to check and certify expertise as a CLG.

The B-CLG is adhering to overarching EBMG statutes and included into the EBMG structure as laid down in the EBMG statutes.

The Branch also seeks close cooperation with the European Society of Human Genetics (ESHG).

II. Purpose/ aims of the Branch

To ensure patient safety, the EBMG recommends very strongly that CLGs engaged in genetic testing for clinical purposes should undergo training and education (normally with a duration of 5 years) that includes all topics expounded in the European curriculum (https://www.ebmq.eu/fileadmin/eshq/EBMG/CLG/Core-Curriculum_2022.pdf). In addition, they should be able to demonstrate competence in the areas defined by the EBMG standards. Overall, the purpose/ aims of the B-CLG are in complete concordance with and embedded in the non-profit goals of the EBMG.

Specific aims of the B-CLG are:

- *recognition of practitioners / non-Medical Doctors working in Human Genetics diagnostics laboratories to be recognized as European registered Clinical Laboratory Geneticists (ErCLG) by the B-CLG.*
- *promote the role of CLGs and educate public and diagnostic community about this.*
- *EU-recognition of ErCLG title based on the EU Directive 2005/36/EC - policy developments and Proposal for modernising the Professional Qualifications Directive = EU Directive 2013/55/EU from 16th January 2016.*

III. Branch Board Members

1. Forms of Branch Board Membership

B-CLG consists of 10 full members who are all experienced CLGs, ideally being registered as ErCLG. All full members have voting rights. Members can be on the board for 2 + 2 years – in exceptional cases also an additional 2 year period. The B-CLG can be supported by working groups (see below).

2. Composition of Branch Board

The 10 full members form the Branch Board, which consists of

Officers

- *Chair*
- *Co-Chair*
- *Secretary*

Members

- *7 equal members, who can be entrusted with different duties.*

3. Eligibility, nomination and election

- *Branch board members should be from EU member states and must be experienced CLGs, ideally being registered as ErCLG.*
- *There are 10 European zones from which one person must be nominated (see <https://www.ebmgeu/668.0.html>; zones may be changed by the present B-CLG at any time – primary goal here is to have representatives from all over Europe and at the same time covering the whole field of human genetics and genomics by corresponding specialists).*
- *Nominations can either come from the present B-CLG, be a spontaneous application to be considered by the B-CLG, or by request of the B-CLG to national contacts of countries from the corresponding zone(s) or all registered CLGs. Nominations have to be received by the chair of the Branch Board by September of each year.*
- *In a voting period, no more than five members shall leave/join the B-CLG per period.*
- *A list of B-CLG members to be (re-)elected is prepared by the secretary – whenever possible one list to be agreed on should be presented. Only for positions with more than one candidate, separate voting must be done on the ballot. The ballot is sent out by the secretary and the votes should be returned to the secretary by each active B-CLG member before the last B-CLG-meeting of the year. In the event of a tie vote, the vote of the chair decides who is elected. This election takes place in even years (see also IV.1).*

4. Duties

- *Branch Board Members need to support the ErCLG registration process by reviewing applications in the platform on request of the chair.*
- *Branch Board Members have to provide 10 multiple choice questions and one to two case-scenarios per year for group 3 country tests.*
- *Each Branch Board member needs to support actively the goals of the branch.*
- *Each Branch Board member commits to fulfil these duties in a written agreement with the chair of the branch when entering the branch.*

5. Mandate periods

2 years for a member (1. January to 31. December); can be renewed as defined above.

6. Termination of Membership

Termination is possible every 2 years (even numbered years), or at any time by request of the member, or by request of the chair of the B-CLG.

IV. Officers:

1. Nomination and election

Chair and Co-Chair are nominated and elected by the members of the B-CLG. Election is carried out in odd years in December and can be done by e-mail or other kind of electronic vote to the secretary.

The Secretary is nominated by Chair and Co-Chair and elected by the members of the B-CLG. Election is carried out in odd years in December and can be done by e-mail or other kind of electronic vote to the Chair.

2. Duties

Chair and Co-Chair represent the Branch at the EBMG level. They work together closely and steer the activities of the branch. They have the main responsibility for the yearly ErCLG registration on the online platform.

Co-Chair or secretary organizes at least four video conferences per year to coordinate ErCLG registration rounds, ESHG-conference associated business and other matters. More, and also in-person meetings can be scheduled, when the branch duties make it appear necessary.

3. Terms of officers

2 years for a Branch Board member (1st of January to 31st of December); can be renewed as defined above.

V. Operations

1. Branch Meetings

- *The Branch Board meeting is the highest authority of the Branch.*
- *The Branch Board meets at least once a year, either in person or virtually; ideally there are at least four video conferences per year; they can but do not necessarily have to be replaced by in-person meetings – e.g. at an ESHG conference. Additional meetings can be necessary for the exams of ErCLG candidates or special duties of the Branch.*
- *One Branch Board meeting can but must not be held in association with the ESHG conference.*

- *The invitation must be sent out at least one week in advance of the Branch Board meeting, and must include date, time, location, minutes from the last meeting, and the agenda.*
 - *At least five Branch Board members must attend, physically or by proxy for another member, for binding decisions of the Branch Board meeting.*
 - *All votes and resolutions of the Branch Board are made with simple majority of votes.*
 - *The Branch Board Chair will lead the meeting. If unable to attend, in line to take over the duty are: the deputy Chair, the Secretary, the (in terms of experience) most senior Branch member.*
 - *Full Branch Board members can give proxy for voting in the Branch Board meeting to another member of the Branch Board. A full member cannot represent more than themselves and one other full member. The Branch Chair and the Secretary shall be notified about proxies at least 48 hours before the meeting, or in case of a sudden emergency preventing the participation of a member as soon as possible and before the opening of the meeting.*
 - *Branch board meetings must be documented in minutes/ protocols.*
2. Working Groups
- *The Branch Board may create working groups for specific tasks serving the goals of the branch.*
 - *Working group chairs are assigned by the Branch Board chair.*
 - *Each working group has an unrestricted number of members. It may comprise of full B-CLG members and external consultants or experts, including previous B-CLG members. At least one full B-CLG member must be part of a working group.*
3. Registration procedure
- There is a registration system for ErCLGs – this was implemented and is operated together with Vienna Medical Academy, Alser Strasse 4, 1090 Vienna, Austria. All details can be found on <https://www.ebm.eu/clg.0.html> and linked subpages.*
4. Examination procedure
- All details can be found on <https://www.ebm.eu/clg.0.html> and linked subpages.*
5. Registry of the B-CLG

The registry containing a list of all currently registered ErCLGs can be found on <https://www.ebmgeu/667.0.html>.

6. Relations with the EBMG Exec/ Council

As regulated in the EBMB statutes

- *The Branch Board reports to the EBMG Exec and to the General Assembly.*
- *The Branch Board seeks exchange with the other Branches of the EBMG and supports their activities where possible.*
- *An opportunity for interprofessional exchange is given, in particular, through the EBMG Council and the General Assembly. The chair and the Co-chair of the Branch Board are members of the EBMG Council, and all full Branch Board members are invited to attend the General Assembly.*
- *The Branch Board nominates the incoming EBMG President, General Secretary or deputy General Secretary according to the rotating system between branches; thus, it is up to the B-CLG to nominate a candidate for the respective positions. The Branch Board seeks a consensus for all nominations for the EBMG Exec (incoming President, General Secretary or deputy General Secretary). If no consensus is reached, a decision is taken by simple majority of votes at a Branch Board meeting (in person or virtually).*

7. Relations with the ESHG

All details can be found in the EBMB statutes. There are no additional formal relations of the B-CLG to ESHG, apart from the fact that B-CLG members may be members of ESHG and have independent of their duty in B-CLG also positions there.

8. Relations with third parties

None.

VI. Finances

Income of the B-CLG comes from registration fees for ErCLG first- and re-registration. This money is meant to be used for:

- *financing of webpage and platform*
- *trips of B-CLG members for exams of ErCLG candidates and to the ESHG conference (if exams are undertaken there) – fees for ESHG conference and travel expenses can be claimed in this special case.*

VII. SOP Amendment procedure

- *Requests / suggestions for SOP changes can be made by each B-CLG member.*
- *An amendment to this SOP has to be taken into consideration if supported by at least three Branch Board members.*
- *Changes to this SOP may be made by two-thirds majority vote of the Branch Board members, i.e. a vote of at least seven of the 10 Branch Board members.*
- *Each Branch Board member has to be given the opportunity to vote on a proposed amendment to the SOP. This can be done at a Branch Board meeting if all members are present, or by circulation procedure.*

VIII. Arbitration Committee

- *The Arbitration Committee of the Branch has the remit to solve disputes regarding issues associated with the Branch Board activities, which may include examination and registration issues such as an appeal from an ErCLG candidate.*
- *The Arbitration Committee of the national contacts of the B-CLG is listed on <https://www.ebmg.eu/666.0.html>. In case of a complaint, a case specific working group is formed as follows: The contact person of the country the complainant is from will act as chair. The chair recruits two further colleagues from the national contacts of the B-CLG list. They work on the case and report their evaluation results to the complainant and the B-CLG (Chair and Co-chair).*
- *The decision of the Arbitration Committee shall be final in its entirety.*
- *The Arbitration Committee conducts the proceedings to the best of its knowledge and belief. The decision shall be taken by a simple majority in the presence of all members and after granting the parties hearing.*
- *Their meetings and votes can be made electronically or in a circulation procedure.*

SOPs published first – 1. March 2023