openEHR
Clinical Program Board (CPB)

Terms of Reference

**Amendment Record**

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Who | Date | Description |
| 1.0.0rc6 | Vebjørn Arntzen MD (UH Oslo, NO),J Holslag MD (Nedap, NL),M Nyström PhD (Cambio, SE),S Ljosland Bakke RN (HelseWest, NO),T Beale (openEHR, UK) | 15-07-2022 | Improved scope. |
| 1.0.0rc5 | R Dunscombe (Imperial, UK),J Holslag MD (Nedap, NL),M Nyström PhD (Cambio, SE),I McNicoll MD (FreshEhr, UK),T Beale (openEHR, UK) | 05-04-2022 | Initial writing, based on openEHR ToR template. |

# Nomenclature

In this document, the following specific terms are used:

|  |  |
| --- | --- |
| Term | Meaning |
| openEHR International Board | Refers to the top board of openEHR International, formally known as the openEHR CIC (Community Interest Company) Board |
| CR | Change Request. Usually created in response to one or more PRs. |
| member of openEHR | A *member of openEHR* is any individual who is either:* a currently subscribed individual or professional member of openEHR OR
* an employee of a currently subscribed Industry or Organisational Partner of openEHR OR
* a member of an Associate Organisation of openEHR.
 |

# Introduction

This document constitutes the formal Terms of Reference for the **openEHR Clinical Program** Board (CPB), as approved by the openEHR International Board.

The intention of these Terms of Reference is to provide a clear basis for:

1. openness to new participation;
2. representation of stakeholders;
3. a meritocratic membership model;
4. quality decision making;
5. transparency of deliverables and activity to the outside world;
6. a defined relationship with the openEHR International Board;
7. professional conduct.

This document does not seek to define all the working structures, plans or communications specific to the work of the Program – such details are generally described in other documents developed by the CPB.

# Clinical Program

The openEHR Clinical Program develops archetypes, templates and terminology subsets for clinical use in an international setting. These are freely available via the web. The following sections describe the structure and scope of the openEHR Clinical Program.

## Structure

The Clinical Program consists of the following entities:

1. The **Clinical Program Board (CPB)** is the governing body of the openEHR Clinical Program;
2. The **Clinical Program Board Expert Panel (CPB Expert Panel)** is an additional group of experts invited by the CPB, which enables inclusion of a larger number of experts to aid in the work program of the Board. The Expert Panel is considered part of the ‘team’, and accordingly has access to internal communications, and access to the CPB tool environment, but has no formal responsibilities or voting rights;
3. The **Clinical Modelling Community**, consisting of healthcare and clinical informatics professionals who have accounts at the main artefact repository, currently Clinical Knowledge Manager, (CKM), and are directly involved in modelling, review, translation and other artefact-related activities.

## Relationship with openEHR International Board

The CPB and its Expert Panel is organisationally subordinate to the openEHR International Board, which gives it authority for running the Clinical Program. The CPB is required to report to the openEHR International Board; the CPB must also obtain approval for proposed changes to these Terms of Reference. In matters of misconduct, the openEHR Board has final authority.

## Aims

The primary aim is to establish the openEHR models as an internationally available authoritative source of clinical data semantics for user with any EHR architecture or interoperability standard, including openEHR.

## Scope

The scope of activities of the Clinical Program intended to achieve these aims includes the following.

1. **Planning and Management**
	1. Roadmap of future releases of outputs of the Program, typically with a 2 year horizon;
	2. Project management: define and manage projects aimed at achieving particular goals.
2. **Methodology**
	1. Artefact governance system & QA;
	2. Methodology manual aka style / patterns guide;
	3. Style manual ([current version](https://openehr.atlassian.net/wiki/spaces/healthmod/pages/304742407/Archetype%2Bcontent%2Bstyle%2Bguide)).
3. **Development**
	1. Archetype development;
	2. Template development;
	3. Terminology value-set development;
	4. Terminology binding and IP management;
	5. Translation management;
	6. Quality control;
	7. Guideline authoring;
	8. Re-use of openEHR models in other technical forms e.g. HL7, OMOP, etc.
4. **Monitoring**
	1. Dissemination and socialisation of artefacts in national/regional programs;
	2. Monitoring use in the field.
5. **Maintenance**
	1. Adding new translations to existing archetypes;
	2. Adding new terminology bindings to existing archetypes;
	3. Error fixes & minor improvements due to feedback from the field;
	4. Manage impact of CKM version upgrades;
	5. Refactoring existing archetypes due to updates to methodology.
6. **Community**
	1. Supporting a high quality clinical community
	2. Facilitating model sharing from vendors, national modelling efforts, etc;
	3. IP agreements relating to archetypes (scores, scales) and terminology;
	4. Public help desk.
7. **Tooling**
	1. Authoring tooling requirements and usability, e.g. refactoring needs;
	2. CKM requirements;
	3. Executable style rules (enforce style guide), design pattern checks / auto-complete.

# Clinical Program Board (CPB)

## Definition

The Clinical Program is managed by the [Clinical Program Board (CPB)](https://www.openehr.org/programs/clinical/board), with the aid of the CPB Expert Panel. The CPB membership consists of community members who are qualified (see below) and who have an interest in achieving the aims of the Program.

The CPB membership is posted online at <http://www.openehr.org/programs/clinical> at an easily accessible location, known as the *CPB home page*.

## Responsibilities

The responsibilities of the Clinical Program Board are:

1. Maintenance of the Roadmap
2. Issue and Change Request (CR) processing:
	1. review of issues;
	2. raising of CRs either in response to issues or de novo, according to perceived need;
	3. implementation of CR changes in the clinical models;
	4. promotion of clinical models through the development lifecycle.
3. Communication to the wider openEHR community of:
	1. requests for input;
	2. roadmap changes;
	3. CR reviews;
	4. completed CRs;
	5. new Releases;
	6. changes to governance documents;
	7. changes to Clinical Program Board.
4. Publishing of the deliverables.
5. Risk management:
	1. identification and management of risks related to planned work;
	2. development of appropriate alternative paths / solutions.
6. Reporting to the openEHR International Board:
	1. routine progress;
	2. risks to planned work and possible alternatives;
	3. resource requirements.

In addition, the openEHR International Board may advise of requirements for releases and prioritisation of work.

Particular members of the CPB may be assigned to handle major scope areas and/or specific responsibilities listed above.

## Size

The CPB is intended to include sufficient members and knowledge to cover the Scope of activities (section 3.4 above) and to execute the formal responsibilities of the Program.

An absolute minimum of five (5) is required.

Maximum membership of the CPB is limited to 20, on the basis that any larger number becomes difficult to coordinate. Note that the size of the CPB Expert Panel is effectively unlimited, but for practical reasons will need to be limited to numbers that may effectively be coordinated in meetings and decision-making.

## Co-chairs

The Clinical Program Board has 1-3 elected co-chairs, who facilitate the work of the Board. The exact number is based on practical needs, and will normally increase with the size of the Board.

The responsibilities of the co-chairs are as follows:

1. to plan and run run CPB meetings and perform appropriate follow-up of tasks;
2. to facilitate the execution of the work of the CPB, mainly by managing completion of modification of task deadlines;
3. to report progress and issues to the openEHR International board;
4. to arbitrate in case of disputes.

## Length of membership

There is no limit on duration of membership of the CPB.

## Establishment

An initial CPB of up to seven (7) members is established by the openEHR International Board as follows:

1. nominations are solicited openly within the openEHR community for candidates satisfying the CPB qualifications (defined below);
2. the nominated individuals will be asked to indicate acceptance (if not self-nominated) and to provide proof of qualification (via a form);
3. accepting candidates are assessed by the openEHR International Board according to the qualification criteria in order to form a final list of accepting qualified candidates;
4. the openEHR International Board will form the Clinical Program Board from the first seven (or fewer) candidates from the list, ranked according to qualifications and representativeness.

## Working Groups

The CPB may create Working Groups (WGs) at any time dedicated to a particular activity for a sustained period. Creation is performed via consensus or vote. Termination of a WG is undertaken the same way.

Membership of WGs may include CPB and/or CPB Expert Panel members, and is on a volunteer basis, with a WG lead being established at the time of creation.

Informal groups or teams may be formed at any time to deal with short term needs, and are not subject to any special governance beyond that of the CPB as stated here.

# CPB Operation

## Basis

The CPB operates in its steady state according to the meritocracy approach established by Apache Foundation and other large open source organisations. Accordingly, new members are added via acceptance by the existing CPB membership, according to the rules defined in this document.

## New Members

Candidature for membership of the CPB is by nomination. New nominations may be made in the following situations:

1. The Clinical Program advertises within the community for a new member, e.g. due to a resignation, or need for more human resource;
2. Community members, typically representing a newly joined organisation may self-nominate at any time.

A new nomination must satisfy the CPB Member Qualifications described below.

## Candidature

The candidate should supply a short CV and other qualifying information providing their:

1. statement of interest in working on the Clinical Program;
2. statement of commitment of time & availability;
3. statement of qualifications, according to Section 4;
4. statement of known conflicts of interest.

## Election

The election process is as follows:

1. A new nomination is sent to the co-chairs of the Clinical Program Board, who will publish it within the committee.
2. A period of up to 28 days may follow to allow for assessment by the current membership. During this period:
	1. the candidate may be asked for more information;
	2. the candidate may be asked to participate in an online or face to face interview;
	3. the nomination may be rejected on formal grounds, such as lack of qualification;
3. If the nomination is not rejected, a formal vote is taken, in which the new member is accepted into the Program based on a super-majority vote of the existing  members.

## Resignation

An existing Program member may resign at any time from the CPB. In this case, the fact and effective date of resignation will be published, and the published Program membership updated accordingly.

If the resignation is of an CPB co-chair, nominations for a new co-chair are called for, and the CPB rules for co-chair election described below followed.

## Termination

A CPB member will be asked to resign in the case of pertinent conflicts of interest.

An CPB member who has been referred to the openEHR International Board by the CPB for disruptive or other unprofessional behaviour, according to the [openEHR Code of Conduct](https://www.openehr.org/governance/code_of_conduct), may be removed by the openEHR International Board following attempts at arbitration.

Where termination leaves a vacancy, the same rules as for resignations are followed.

## Co-chair Elections

Co-chair positions last 2 years. Elections of co-chair(s) by the Program Board are held every 2 years at a fixed date, as well as in the case of resignation of a co-chair. At election time, the positions of co-chairs who have spent 2 years in the position and/or who have resigned are considered vacant. A vacating co-chair may re-nominate or be nominated for a successive term.

The co-chair election process is as follows:

* Existing co-chairs formally indicate resignation to the CPB;
* During the period prior to new co-chairs being elected, a previous co-chair (or his/her nominee) volunteers to execute the election process;
* If the CPB wishes to agree a change in the number of co-chairs, it should do so and announce the intended number;
* Nominations for co-chairs are requested within the CPB;
* A period of up to 2 weeks, or less, by consensus, is allowed for gathering of nominations;
* The nominations are announced and posted clearly within the CPB;
* The number of open co-chair positions is the originally announced number or the number of nominees, whichever is lower;
* At the close of the nomination period, a vote is run either in a meeting or asynchronously; in the latter case, up to one week may be allowed for votes to be received;
* A separate vote is made by each CPB member for each open co-chair position, limited by the
* Votes are tallied for the nominees and the new co-chairs are declared as the nominees with the highest number of votes according to the required number of co-chairs;
* The new co-chairs are announced publicly and indicated on the CPB home page.

A system of alternating / rotating terms may be used to spread the workload and experience across the CPB membership, although this is not strictly required.

Election to co-chair position requires a super-majority CPB membership vote.

# CPB Member Qualifications

A new candidate for election to the CPB must be **must be a member of openEHR** (as per Definitions section) and should demonstrate the following qualifications.

## Skills and Knowledge

The following qualifications are required for membership of the CPB.

1. An understanding and acceptance of the [openEHR mission](https://www.openehr.org/about/vision_and_mission);
2. Health informatics and/or clinical background: a demonstrable knowledge of key health informatics areas such as EHR, terminology, clinical environments, public health, medical research;
3. openEHR experience: at least 1 year of active participation in the openEHR community.

Other areas of experience such as knowledge engineering and artefact governance are greatly valued.

## Commitment

The following commitment is agreed to.

1. An expressed interest in actively working on the Program;
2. Agreement to work as an expert for the aims of the Program rather than commercial or other goals of their employer;
3. Availability to attend ideally 70% of calls / meetings over the year;
4. Availability to contribute sufficient time to perform the work, generally a few hours a month;
5. Maintenance of openEHR membership.

It is up to the CPB to agree the engagement mode of any particular member, which may be more or less asynchronous, depending on time-zone and other factors.

## Conflicts of Interest

Any potential conflicts of interest must be declared by the candidate, and the candidate must agree to indicate any such conflict of interest in discussions and decision-making processes of the Program in which they are involved.

# CPB Expert Panel

## Definition

The CPB Expert Panel is an adjunct group of experts invited by the CPB to provide expert input and guidance.

## Size

There is no formal size limit on the CPB Expert Panel, but it is expected that it be limited to a number such that the total number of CPB + CPB Experts Panel members may comfortably participate in calls and meetings (even if not all members actually do at all times).

## Nomination

Individuals are nominated to the CPB Expert Panel by a CPB member on the basis of specifically recognised expertise relevant to the work of the CPB.

## Candidature

A nominee becomes a candidate for invitation following a CPB discussion and general consensus, or a vote if needed. The candidate is asked to provide:

1. a CV or similar description of qualifications;
2. a declaration of any conflicts of interest;
3. a declaration that he or she is willing to participate on an ad hoc basis, including review of specific issues, Change Requests (CRs) and strategic questions to do with deliverables that are in the area of the candidate’s expertise.

Following a positive vote, the candidate is invited to join the CPB Expert Panel.

## Resignation

A CPB Expert Panel member may resign at any time.

## Termination

A CPB Expert Panel member will be asked to resign in the case of pertinent conflicts of interest.

A CPB Expert Panel member who has been referred to the openEHR International Board by the CPB for disruptive or other unprofessional behaviour, according to the [openEHR Code of Conduct](https://www.openehr.org/governance/code_of_conduct), may be removed by the openEHR International Board following attempts at arbitration.

## Length of Membership

There is no time limit on CPB Expert Panel membership.

## Rights

CPB Expert Panel members have access to all the same materials and resources as the CPB, including private discussion groups and modification rights to Change Requests, private wiki pages and internal documents.

CPB Expert Panel members do not participate in formal voting, including issue progression or CR acceptance.

## Responsibilities

The primary responsibility of members of the CPB Expert Panel is to participate in particular CPB work items to which their expertise is relevant, including review and/or proposal of changes to deliverables, technical directions and so on.

# Decision-making

Decisions are taken by the CPB on two categories of item: governance and routine work items (i.e. items relating to deliverables). Governance questions require a super-majority vote, while routine work items require a simple majority.

## Voting Rules

A *simple majority* is defined as:

1. For an odd number of members, the integral number above the total x 0.5, e.g. 4 out of 7, 6 out of 11 etc;
2. For an even number of members, half the member count plus one, e.g. 4 out of 6, 6 out of 10 etc.

A *super-majority* is defined as:

1. The integral number above 2/3 x number of members.

For the purposes of this document, the term *majority* is always with respect to the total CPB membership, rather than the number of members present at a particular meeting or call. This may mean that although a meeting or call has quorum, it may not have a majority in attendance in situations where a vote is needed. In such cases, a vote may be run asynchronously (see Formal Vote Process below).

## Quorum

For the purposes of formal voting on routine matters requiring simple majority, a regular meeting or call is regarded as quorate with a simple majority of CPB members present.

For meetings or calls whose objective is to undertake a vote requiring super-majority, 2/3 of the membership is required to constitute a quorum.

## Consensus Process

Decisions on change and release management are primarily made by consensus, i.e. agreement of a quorum of members with no serious objections voiced. Where there are objections, the following process will be used:

1. the co-chairs will manage a more formal round of discussions which seek to expose the points of difference and disagreement;
2. If this fails to result in consensus, the co-chairs may initiate either a formal vote (see below) or an open community review of the issue with a fixed timeline, whichever appears most appropriate;
3. in the case of a community review, the results will be the basis of a further round of CPB discussion aimed at finding a consensus position;
4. in the case of a formal vote, the procedure in CPBtion 5.4 is followed.

Where there is any remaining dispute, it can be referred by the CPB co-chairs to the openEHR International Board for resolution. This may require an extraordinary meeting / conference.

## Formal Vote Process

Sometimes a formal vote will be required. This can only occur when there is a quorum of 2/3 of the CPB members available in a face to face meeting or live teleconference / webconference. The procedure is as follows:

1. a motion is tabled;
2. the motion is CPBonded;
3. votes are gathered;
4. vote by proxy is allowed, supported by a written confirmation (e.g. email) from the absent voter;
5. the motion is considered passed if a simple majority of the CPB membership is obtained.

Asynchronous voting may be used once a motion is tabled and CPBonded in a meeting. A period of at least a week and no more than 28 days is stated for the gathering of asynchronous votes.

# Meetings

## Venue

Most work of the CPB is performed via teleconferences, and asynchronously, via discussion groups, online issue trackers, CKM and other tools.

## Frequency

Calls / meetings of the CPB should be held on average at least once a month. This may vary for reasons of holidays, external events etc.

## Attendance

CPB members should attend CPB meetings at least 70% of the time.

CPB Expert Panel members are encouraged to attend as often as possible, particularly when requested for meetings whose agenda relates to specific Expert Panel member knowledge areas.

Guests may be invited to meetings by consensus of the CPB.

## Chairing

Calls and meetings are chaired by any available co-chair, by agreement among co-chairs. In the event of absence of all co-chairs, a proxy nominated from the CPB membership may chair a meeting.

## Note-taking

Minutes or appropriate notes will be taken for each call and meeting, including agenda, main discussions, decisions and actions. These should be made visible on e.g. a dedicated area on the openEHR Confluence site or a similar location such as Discourse.

# Reporting

A report of Program activity to the openEHR International Board is to be provided by the CPB co-chairs quarterly as well as on request. Other issues, including identified risks to progress and resourcing problems are to be reported to the openEHR International Board in a timely fashion.

# Deliverables

## Identification

<in general terms, indicate that deliverables are identified>.

## Change Management

<in general terms, indicate that deliverables are formally change managed>.

## Issue Reporting

<indicate that there is a way for community to raise issues with deliverables>.

# Professional Conduct

CPB members are required to respect the [openEHR Code of Conduct](https://www.openehr.org/governance/code_of_conduct).

In order for the CPB development and decision-making processes to run efficiently, and to provide an enjoyable experience for participants, contributions should follow the following guidelines:

1. contributions to discussions and debates should be based on considerations (e.g. technical, clinical) relevant to the matter at hand;
2. debates (online and face to face) should be conducted in a professional and scientific manner, with a willingness to follow the governance principles stated here, and in cases of dispute, to accept consensus, votes, and the outcome of any arbitration.

In the event of a member's participation causing problems, the matter should be referred to in the first instance to the chair of the Clinical Program Board, and if necessary, an extraordinary meeting or meetings called for the purpose of arbitration. Arbitration will proceed with the Clinical Program Board. If an agreement cannot be reached this way, the matter will be referred to the openEHR International Board.

# Evolution of these Terms of Reference

The governance structures and procedures described above will inevitably need to change over time. The process for proposing and executing changes is as follows:

1. A change can be proposed by anyone within the Clinical Program, or by the openEHR International board. This request should include a statement of the problem being experienced with the current governance.
2. Requests for change are welcome from the wider community, but need to be advocated for by an existing CPB member;
3. The CPB co-chairs undertake to refine the request into a specific change in the rules that addresses the problem.
4. This is then published within the CPB for review for a stated period, e.g. 28 days.
5. Further refinement may be carried out on the back of the review.
6. When no further modifications are proposed, the CPB holds a vote to accept the modified version of the governance document; this must pass by a super-majority;
7. A final detailed proposal is presented to the openEHR INTERNATIONAL board by the CPB co-chairs.
8. The openEHR International Board will notify its acceptance or otherwise within a period of 2 weeks;
9. If accepted, the change is publicly notified to take effect on a certain date, at which time the governance provisions in these Terms of Reference are modified accordingly;
10. If not accepted, an explanation is provided as a basis for further adjustments by the CPB, after which the new version may be re-submitted.

The openEHR International Board can unilaterally request a change to these Terms of Reference, usually in order to ensure alignment of governance provisions of the Program with the organisation as a whole. Such changes may be made and accepted without undertaking the review process described above.