

GERCOR ASSOCIATION: BYLAWS AND INTERNAL RULES

I. BYLAWS

Article 1: Formation – Name

The undersigned and all persons who shall later adhere to the present Bylaws have created an association called “GERCOR”.

Article 2: Purpose

The purpose of this association is to improve the care of patients affected by cancer by developing clinical research in the scope of an independent, multidisciplinary and multi-focussed group.

For this purpose, to encourage individual initiative, facilitate the implementation of and perform international-level studies selected by a scientific council set up by the internal rules.

Article 3: Term

The association’s term is without limitation.

Article 4: Registered Office

The association’s registered office shall be the Hopital Saint Antoine, Paris 12th. It may be transferred elsewhere within the same *département* [≈ county] by a decision by the board of directors.

Article 5: Members

The only persons eligible for membership of the association shall be those persons or entities involved in pooling their knowledge and activities on a permanent basis in the interest of the goal described at Article 2.

There are three categories of members:

- full members
- associate members
- honorary members.

Article 6: Joining

Any application to join this association, made in writing, is submitted to the board of directors which will decide on this admission without being required to give reasons for its decision, whatever it is.

Article 7: Loss of membership status

Membership of the association shall be lost:

- (1) by resignation sent to the association's chairman in writing;
- (2) for an individual, by death or as a result of deprivation of civic rights;
- (3) for an entity, if it is ordered to restructure by the courts or dissolved, for any reason whatsoever;
- (4) for non-payment of dues, if dues are required, twelve months after the due date;
- (5) by exclusion, ordered by the board of directors, for the reason of non-compliance with the internal rules and any other serious grounds, to be assessed by the board of directors; in such a case, the candidate for exclusion shall be asked by registered letter to supply written explanations;
- (6) by the loss of specific attributes, laid out in Article 5, paragraph 2 hereof, which are required by the various categories of members.

Article 8: Resources

The association's resources are all those which are not forbidden by the laws and regulations in effect.

If it is decided to charge membership dues, its amount shall be set by the board of directors; it shall not be refundable to the members of the association.

Article 9: Board of directors

The association is managed by a board of directors made up of 24 members elected by the general meeting from among the members of the association who fulfill the following conditions:

- if it is an individual; that he/she is an adult, has not been deprived of civic rights, is not under judicial protection on account of having diminished faculties or under statutory or temporary guardianship;
- if it is an entity, it must not be under court-ordered liquidation or in dissolution, for any reason whatsoever;
- he/she/it must not have already performed the office of director in an association with similar or identical goals.

Any member of the board who/that does not comply with any one of these conditions is subject to forced resignation.

Article 10: Reappointment of board members

The board is reappointed in full every two years by the general meeting of members of the association via secret ballot. Members voted out are immediately eligible for reelection only once.

If there is a vacancy pursuant to a death, a resignation or a loss of the attributed required by Article 9, the board temporarily replaces its members. They are replaced officially at the next general meeting. The powers of the members elected in this way terminate at the time that the replaced members' term would have expired.

If all the positions on the board are vacated, a general meeting shall be called by a member of the association with the sole agenda item of either electing new board members or dissolving the association.

Article 11: Powers of the board of directors

The board is invested with the broadest powers to take all decisions that are not reserved for the general meeting of members.

It shall rule on the admission and exclusion of members.

It shall delegate any of its prerogatives to any of its members.

It shall report on its management to the annual general meeting of members.

Article 12: Operation of the board

The board shall meet at least once every six months and each time that it is called by its chairman or by more than 50% of its members.

It shall decide issues on a simple majority basis of the members present or represented. Minutes shall be kept of the board meetings.

Article 13: Chairman

The board shall elect its chairman from among its members.

The chairman is elected for two years, but his term of office as chairman cannot exceed his term as board member.

The chairman is immediately eligible for reelection only once.

Article 14: Powers of the chairman

The chairman is endowed with the power to represent the association in all its civil affairs. In particular, he may represent the association in court.

He may delegate this power to any other member of the board, in a specific written document. In the case of a court appearance, he can be replaced only by a representative acting under a special proxy.

Article 15: General meeting, composition and powers

The general meeting is made up of all the members of the association who are up-to-date with their dues, if any is requested, as at the date the meeting is called.

It alone has the power to:

- appoint (reappoint) and dismiss members of the board of directors;
- amend the Bylaws and the internal rules, except for transfer of the head office within the same *département* [\approx county] which is the prerogative of the board of directors, and announce the dissolution of the association;
- control the management of the board of directors.

Article 16: Operation of the general meeting

The general meeting shall meet once per year and each time that it is necessary, when called by either the chairman of the association, or by at least 50% of the members of the board, or at least 50% of the members of the association (with the exception of the circumstance mentioned at Article 10, last paragraph).

It shall make decisions on a simple majority basis of the members present or represented. By sending a blank proxy form, any member of the association lodges a vote “for” the adoption of the draft resolutions on the agenda by the author of the notice of meeting, and a vote “against” the adoption of any other draft.

No amendment may be made to the Bylaws or of the internal rules, and the association may not be dissolved, unless at least 75% of the members are present or represented.

Article 17: Internal rules

Internal rules shall be drafted by the board of directors to set the procedures for performing these Bylaws and the association’s activities. They must be approved by the general meeting of members of the association under the conditions specified at Article 16 for the amendment of the Bylaws.

These internal rules are binding upon all the members of the association.

Article 18: Dissolution of the association

In the event that the association is dissolved, the general meeting of members:

- appoints one or more receivers;
- takes any decision relating to the devolution of the net assets remaining without being able to attribute to the association’s members anything other than their contributions.

II. THE INTERNAL RULES

1. Resources

The association's resources are all those which are not forbidden by the laws and regulations in effect.

The association shall not pay fees to its members.

The amount of the annual membership dues shall be:
full and associate members who are doctors: 500 francs
interns and non-doctors: 1 franc.

Subsidies shall be sought, particularly from the pharmaceutical industry. The fees for therapeutic trials committing the pharmaceutical industry shall be directly charged under the terms of an agreement between the group and the laboratory.

2. Operation

The group shall promote studies outside the pharmaceutical industry.

It shall have:

- a permanent secretariat for mailings, requirements to do with studies, inclusion of patients and the organization of meetings;
- clinical research officers to verify data collection

The group will:

- run an annual plenary session
- run meetings of the investigators and participants in studies underway
- publish a report on activity twice yearly.

3. The scientific council

1. The scientific council

The members of the scientific council shall all be full members who wish to be members and who are prepared to fulfill their obligations.

The obligations of the members of the scientific council are:

1. to evaluate any new project presented to the group and provide a response within two weeks
2. to select, if necessary, co-investigators and participants in the new studies
3. to select the members of the scientific committees
4. to arbitrate any disputes that may arise with the investigators and the assessment committee of a study

5. to appoint the members that represent the group in relations with other groups.

2. The scientific committees

The scientific committees are made up of full members who volunteer and are approved by the scientific council.

There is one scientific committee for each large cancer site, whose members have been investigators or have published in relation to the pathology concerned.

The scientific committee is responsible for assessing the therapeutic protocols.

The scientific committee appoint the assessment committee for each study.

The scientific committee may co-opt one or more experts from outside the group.

3. The assessment committees

The assessment committees are made up of members of the scientific council who volunteer and are approved by the scientific council.

The assessment committee is responsible for monitoring and verifying the good clinical practices during a study.

The assessment committee shall be entitled to propose a change of investigator, the rejection of a participant and the early halt to a study that is not achieving its objectives.

4. The stages from the plan to the completion of a study

stage 1: assessment of the medical and scientific importance of the plan

- The investigator who wishes to perform a study sends a summary of the study to the secretariat
- The secretariat sends the summary to the members of the scientific council
- The members of the scientific council notify the secretariat within two calendar weeks of their individual opinion depending on the usefulness of the plan and the commitments under way in the same pathology
- If a majority of the opinions are negative, refusal is immediate.
- If a majority of the opinions are positive, go to stage 2.

stage 2: assessment of feasibility

- The summary of the study is sent to the full members and/or to the outside participants with a questionnaire of commitment including the number of patients that can be included
- The investigator and the board make an estimate of the costs and the financing required
- If the number of patients that can be included, the costs and the financing required are realistic, go to stage 3.

stage 3: selection of participants and investigators

- The investigator and the board select the participants based on the interest expressed and the number of patients that can be included
- Co-investigators are taken on with an obligation to multidisciplinary

stage 4: protocol drafted and administrative requirements performed

- Within 4 weeks, the investigators draft the protocol and the data reception log
- Protocol and data reception log submitted to participants and to the scientific committee
- Administrative requirements by the secretariat: insurance, DRASS, CCPPRB
- For non-AMM studies, after adoption by the CCPPRB, depending on the decision of the scientific council, the secretariat and the investigators-coordinators fulfill any required hospital formalities (declaration to the management and agreement with the pharmacy) and any ministerial and regulatory formalities.

stage 5: start of study

- Preliminary meeting of investigators
- On-site meeting, if possible in the presence of the principal investigators or the clinical research physician

stage 6: obligations during the progress of the study

- Meetings with investigators and participants at least twice a year
- Evaluation of the progress of the study: pace of inclusion, compliance of participants with commitments
- Evaluation of good clinical practices: consent, source file, data reception log
- Presentation at a plenary session.

stage 7: evaluation of the progress of the study

An assessment committee, in the presence of the investigator-coordinator(s), makes the decision whether to continue the study or halt it early, depending on the difficulties, the pace of inclusion and the pressure of new projects that are more ambitious in the same indication. Any decision to halt must be approved by the scientific council.

stage 7: closure of the study

- The secretariat notifies the participants of the halt to the study and deals with the administrative requirements
- The investigator-coordinator(s) write their preliminary report within 4 weeks
- The participants that deserve to be co-authors are notified and give their consent to participate in the drafting of the initial publication or they appoint a member of their team who actually participated on the study in their institution
- The authors write the final article within two (2) months and submit it to the members of the board for internal assessment before submission to the journal of their choice or one suggested by the board.

Progress of a study

investigator

summary

secretariat

(2 weeks)

scientific council

negative opinion positive opinions

active members

number of patients that can be included costs and the financing required

(2 weeks)

board

selection of the participants

selection of one or more co-investigators

protocol drafted

(4 weeks)

submission to and approval by the scientific committee

administrative requirements performed

study set up

meetings of investigators | meetings of assessment committee

continue stop

closure - administrative requirements

preliminary report

(4 weeks)

appointment of co-authors

article

internal assessment

submission

(2 months)

5. Rules of publication and collaboration

1. Publications

The group's articles may be signed by ten authors (in special circumstances more if the journal allows it or if the importance of the work merits it), in the following order, which must be validated by the scientific council:

- 1st. the principal investigator
- 2nd. the best participant
- 3rd. the co-investigators according to their participation and giving preference to the young

Then: the other participants

The statistician has the status of co-investigator.

To comply with the concept of multidisciplinary and to facilitate access to the publications, it is advised that a team should appoint a single participant per study. The non-authors will be cited in a schedule in the order of their participation.

The group will be mentioned in the publication.

2. Collaborations

Outside collaborations

The rules for authors apply to an outside collaboration on a study by the group.

If a group wishes to participate as a group, it may choose a participant or one investigator will represent the whole group.

Intergroup studies

The rules and decisions will be taken at the start of the study.

The participants shall declare their group.

The group will be cited.

Participation in outside studies

These are free, individual and do not commit the group.

The group may recommend a participation when the usefulness justifies it and it would not compromise any studies under way.