

# HEAD AND NECK CANCER INTERNATIONAL GROUP (HNCIG)

## STATUTES

### 1. DEFINITION

The Head and Neck Cancer Intergroup (HNCIG) is an organization comprised of international and national Cooperative Research Groups and Sites performing clinical trials and meta-analyses in head and neck tumors, which includes but is not restricted to tumors originating from the upper aero-digestive tract. HNCIG studies are those head and neck tumor studies involving any two or more HNCIG member Groups or Sites.

### 2. MISSION STATEMENT

The HNCIG aims to promote and conduct high quality clinical trials and meta-analyses in order to improve outcomes for patients with head and neck tumor. This will be achieved through international collaboration, a strong sense of common purpose, shared expertise, and mutual respect among the members.

### 3. AIMS

- Promote international collaboration
- Promote clinical and translational research
- Perform studies in rare tumors
- Stimulate evidence-based medicine
- Support educational activities
- Harmonize clinical trials and translational research guidelines

### 4. MEMBERSHIP:

#### *FOUNDING MEMBER GROUPS:*

**Founding members are those Cooperative Groups that were invited to the Nice Meeting, February 12, 2015, plus the Irish Cooperative Oncology Research Group (listed in Annex A). These members must meet the criteria for membership and agree to comply with the rules as outlined below.**

### *CRITERIA FOR ADDITION OF NEW MEMBER GROUPS TO THE HNCIG*

Members of the HNCIG are Cooperative Clinical Research Groups focused on the successful conduct of head and neck cancer clinical trials.

Any international or national research Group performing clinical trials in the field of head and neck cancer can apply for membership of the HNCIG if:

- It has or is able to perform phase III clinical trials in head and neck tumor(s) under GCP conditions, with sufficient data management and statistical support, and has satisfied at least one of the following three conditions:
  - It has conducted at least one phase III clinical trial in the field of head and neck oncology
  - It has participated or is participating in at least one intergroup phase III trial or can be identified as a cooperative research group in a report of an intergroup trial in the past
  - It has reported on a phase III trial as a cooperative research group
- Is willing to support attendance of its representatives at the meetings of the Board of Directors and General Assembly of the HNCIG twice yearly with representation and active participation in the standing committees and working groups;
- It is committed to pay annual dues;
- It agrees to comply with GCP

Groups that perform meta-analyses of head and neck cancer clinical trials are eligible to join as advisory members to the intergroup.

### *CRITERIA FOR ADDITION OF NEW MEMBER SITES TO THE HNCIG*

Large individual sites that have an established track record in running phase III trials as a single institution can be considered for membership. This may be particularly relevant in countries where a national head and neck trial group does not exist. They must meet the membership criteria outlined above.

### *PROCEDURE TO ADD A NEW MEMBER GROUP OR SITE TO THE HNCIG*

A potential new Member Group or Site should express interest to join the HNCIG by completing the Membership Application Form and submitting it to the Membership Committee. The Membership Committee will evaluate the application and provide their recommendation to the next Board Meeting. At that time, Board Members will vote on admission of the new group, which can be approved by majority decision.

Prior to this approval, a Group or Site may send one representative to a single HNCIG general as an observer without voting privileges; after that it must apply for membership to continue to attend general meetings. If a Group or Site is unable to meet the membership requirements after attending once as an observer, an extension may be accorded to allow continued attendance of General Assemblies by one observer from that Group or Site provided that the Board agrees that there is evidence of that the observer Group or Site is making progress towards fulfilling membership criteria.

When a Group or Site that performs clinical trials joins the HNCIG, the chair of that organization's Head and Neck Cancer section should appoint up to 3 representatives to attend HNCIG general assembly meetings (ideally, chosen to represent the principle disciplines of medical, surgical, and radiation oncology) and should designate one of these representatives as a voting Board member. Organizations that perform meta-analyses but do not directly conduct clinical trials should appoint a representative to the General Assembly and to the Board in an advisory but non-voting capacity.

#### *CRITERIA FOR GROUPS OR SITES TO REMAIN A MEMBER OF THE HNCIG*

- Group and Site Members are expected to contribute actively in the HNCIG, i.e., participate in at least one of the HNCIG trials on behalf of the HNCIG every 5 years
- Groups and Site Members will be reviewed by the Membership Committee every 3 years to ensure that the member:
  - has actively participated in at least one HNCIG study as acknowledged by accrual
  - has provided evidence that it has been GCP compliant in the HNCIG trials in which it has participated;
  - has paid annual dues;
  - complies appropriately with the Statutes and Bylaws of the HNCIG

## 5. PARTNERS

### *ADDITION OF PARTNERS*

HNCIG Board Members may recommend to the Membership Committee partners from, for example, industry, advocacy, or government regulatory authorities. That Committee will evaluate the partner and make their recommendation at the next Board of Director's meeting as to whether that partner should be accorded observer status at subsequent General Assemblies. The Membership Committee will determine if a partner is considered commercial.

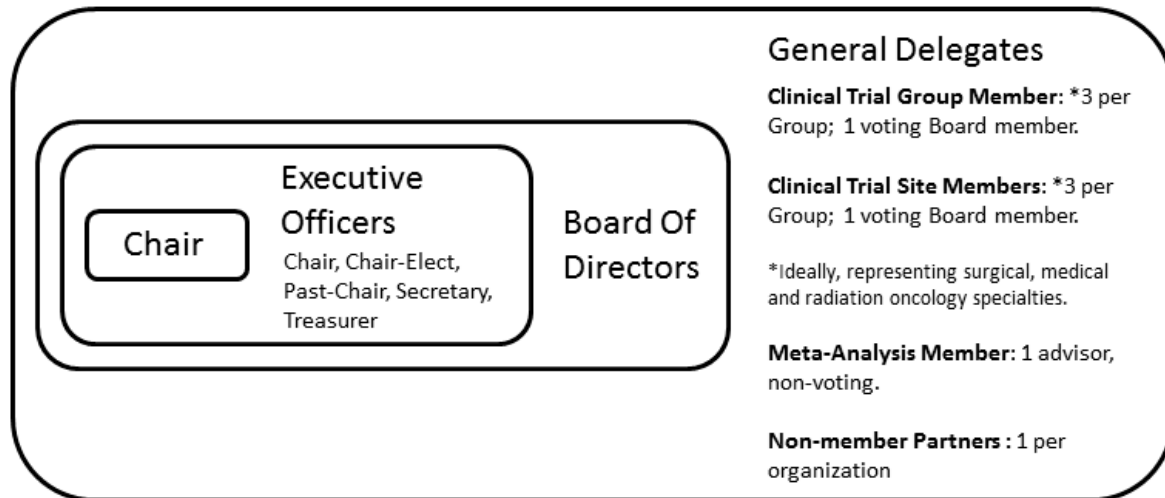
- These partners are not considered members and have no voting privileges.
- The Membership Committee will determine if a partner is considered commercial. Commercial partners will pay an annual commercial partner fee.

### *REMOVAL OF PARTNERS*

The Membership Committee will review commercial partners annually. If such partners are more than 6 months in arrears for fee payment they will receive a warning from that committee. If they are more than 12 months in arrears, their partnership with the HNCIG will be discontinued.

## 6. STRUCTURE

The overall structure of the HNCIG is illustrated below:



### A. General Delegates

General Delegates participate in the General Assembly.

- HNCIG Member Groups and Sites performing clinicals may appoint up to 3 General Delegates. These persons should be identified to the HNCIG Secretariat by the Chair of the respective Member Group or Site's Head and Neck section. Multidisciplinary representation (surgery, radiotherapy, medical oncology) is encouraged.
- Groups performing meta-analyses may appoint one General Delegate.
- Non-member partners may identify to the HNCIG Secretariat one person to serve as General Delegate.

### B. Board of Directors

The Board of Directors is the decision-making body within the HNCIG.

#### *Directors*

- Each HNCIG Member Group will appoint one Director. The chair of each Member Group will specify to the HNCIG Secretariat which one of their General Delegates will serve on the HNCIG Board of Directors. That designee will serve on the Board of Directors until a replacement is named. These directors each have one vote.
- The organization that is functioning as Secretariat will have an ex-officio, but non-voting seat on the Board of Directors.
- A co-chair of the U.S. National Cancer Institute Head and Neck Scientific Steering Committee will have an ex-officio, but non-voting seat on the Board of Directors.

- In the absence of any of the above Directors at a Board meeting, the respective organization may appoint a substitute/proxy.
- The immediate Past Chair of the Board of Directors will have a voting seat on the Board of Directors. The Past Chair position does not count against the number of board seats available to Member Groups.
- The Chair of the Board of Directors has a voting seat on the Board of Directors. The Chair position does not count against the number of board seats available to Member Groups or Sites.

### *Quorum*

A quorum for the transaction of business at meetings of the Board shall be the smallest whole number that is not less than a majority of Directors, and no business shall be transacted at any meeting unless the requisite quorum is present in person or electronically at the commencement of such business.

### *Voting*

The Board of Directors has the power to make decisions concerning all business matters provided that a quorum of Directors is present. The HNCIG Chair will conduct all votes, which will be decided by simple majority, with the exception of votes regarding amending statutes (see Amending Statutes, below). In the event of a tie, the HNCIG Chair may cast the deciding vote.

## **C. HNCIG Executive Officers**

The HNCIG Executive Officers are the Chair, Chair-elect, and Past-Chair, Secretary, and Treasurer.

### *Chair, Chair-Elect, and Past Chair*

#### **Duties of the Chair**

- Run all Board of Directors and General Assembly meetings. In the event that the Chair is not available for a specific meeting, these duties will devolve upon the Chair-Elect, Past-Chair, Secretary and Treasurer in that order.
- Act as official spokesperson of the HNCIG
- Provide final approval of all expenditures
- Assure compliance with HNCIG statutes
- Oversee activities and personnel of the HNCIG Secretariat

#### **Duties of the Chair-Elect**

- Any duty delegated by the Chair

#### **Duties of the Past-Chair**

- To provide continuity and corporate memory for the HNCIG, to assist transitioning chairs and chairs-elect, and any duties delegated by the Chair.

#### **Election Procedure**

- The Chair will rotate regionally among clinical trial group or site members based in North America, Europe and Asia/Oceania.
- The term will be five years: one year as Chair-Elect, two years as Chair and two years as Past-Chair.
- The clinical trial group or site that will deliver the next Chair-Elect will be appointed by the majority vote of the Directors at the Board Meeting preceding the commencement of the new term of office. Clinical trial groups from the region of the current Chair will not be eligible to appoint a chair (e.g., if the chair is from a North American group, then other North American groups will not be able to submit a nominee). The elected clinical trial group or site will nominate an individual to serve as Chair-Elect.
- The Board of Directors will vote to confirm the Chair-Elect. If the nominee is not confirmed, the clinical trial group or site will nominate another individual. This process will repeat until a nominee is confirmed by the Board of Directors or the clinical trial group or site declines to appoint another nominee, in which case the Board of Directors will elect another clinical trial group or site, restarting the process.

#### **Special considerations concerning the founding chair**

- These override the above. Subsequent to enactment of these statutes, the Founding Chair will be elected by the initial Board of Directors. The term of the founding chair will be three years. During this time, there will be no Past-Chair. A Chair-Elect will be elected in the last year of the Founding Chair's three year term. Five years after approval of these statutes, this paragraph will automatically be deleted from the statutes.

#### *Secretary and Treasurer*

##### **Duties of the Secretary**

- Respond to inquiries from the Board of Directors, and the chairs of HNCIG committees and working groups.
- Assist the Chair and Board in observance of these statutes.
- With assistance from the Secretariat:

- Develop agendas and produce minutes from HNCIG Board of Directors Meetings and General Assemblies, and ensure that such documents are also produced and recorded by HNCIG committees and working groups.
- Develop and maintain a calendar for HNCIG events.
- Develop and maintain the group website and online repositories.
- Disseminate materials as directed by the Board and Executive Committee
- Assist with editing HNCIG documents and manuscripts.
- Keep the HNCIG roster up to date.

#### **Duties of the Treasurer**

- Maintain transparent and accurate financial records for the HNCIG
- Obtain Chair approval for all expenditures over and above an amount determined by the Board.
- Correspond with Members and Partners regarding dues and fees.
- Prepare an annual report for the Membership Committee about timelines of dues and fees payments.
- Prepare an annual financial report for the Board of Directors

#### **Election Procedure**

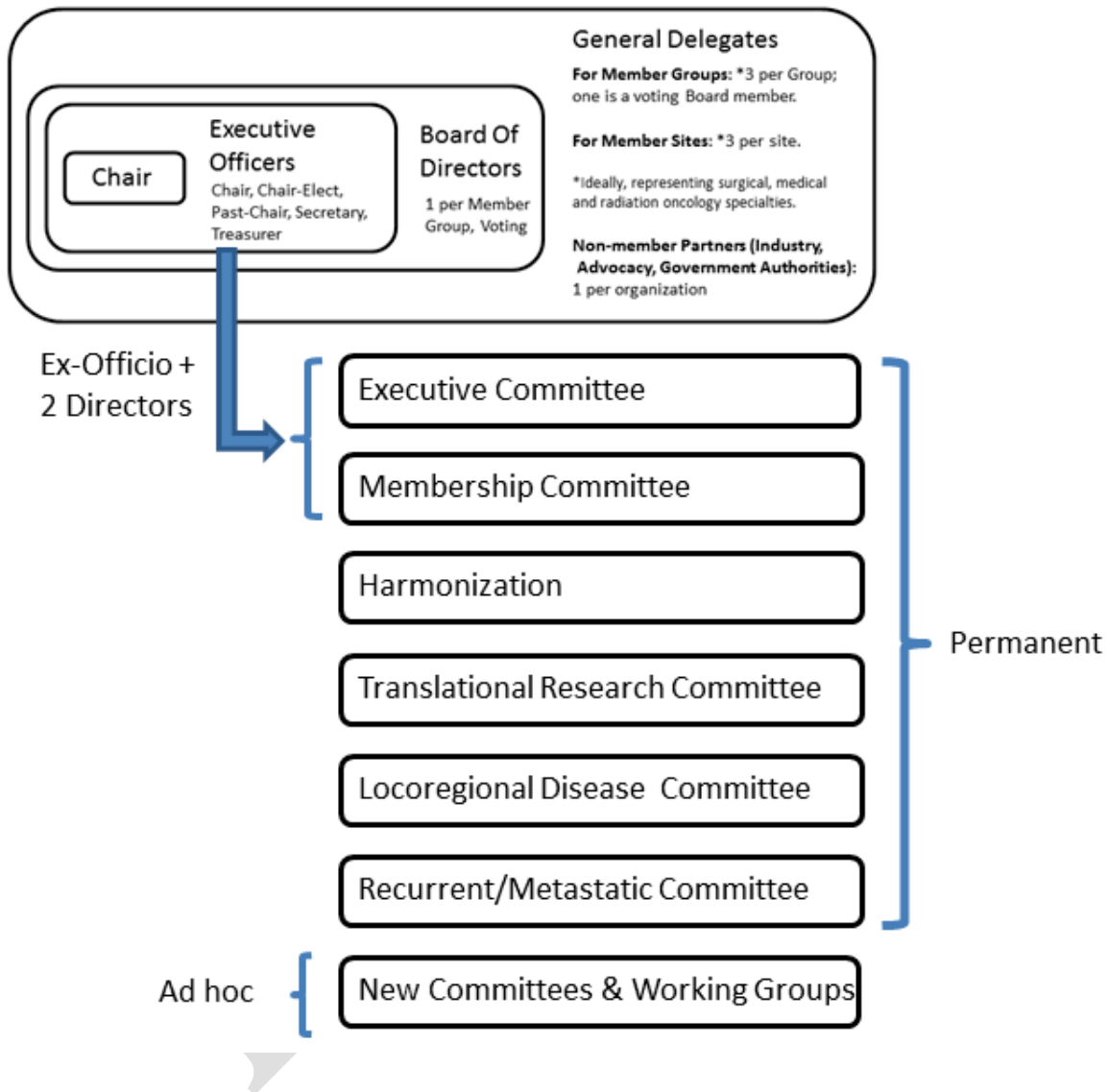
- Both secretary and treasurer positions will rotate among the member groups.
- Both terms will be three years and can be renewed once.
- Prior to the new term of office for the Secretary, the Board of Directors will elect a clinical trial group or site to nominate a new Secretary. Similarly, the Board will nominate a clinical trial group or site to nominate a new Treasurer. If the nominee is not confirmed by the Board of Directors for a given position, the respective elected clinical trial group or site will nominate another individual. This process will repeat until a nominee is confirmed or the elected clinical trial group or site declines to appoint another nominee, in which case the Board will elect another group, restarting the process.

#### **Special considerations concerning the Founding Secretary and Treasurer**

- The positions of Founding Secretary and Treasure will be filled by the same process as the Founding Chair. Five years after approval of these statutes, this paragraph will automatically be deleted from the statutes.

## 7. COMMITTEES

The following will be Permanent Committees within the HNCIG. Additional committees and working groups can be convened and dismissed at the discretion of the Board of Directors. All committees and working groups are responsible to the Board of Directors.



### *EXECUTIVE COMMITTEE*

During the intervals between meetings of the Board of Directors, the Executive Committee does possess and may exercise all the powers of the Board in the management and direction of the affairs and business of the Group.

The Executive Officers of the Board of Directors will serve ex-officio on this committee, which will be chaired by the Chair of the Board of Directors. At least every two years, the



Board of Directors will elect at least two additional Directors to serve on the Executive Committee.

The Executive Committee shall have power to fix its quorum at not less than a majority of its members. No business may be transacted by the Executive Committee except at a meeting of its members at which a quorum (majority) of the Executive Committee is present.

Directors not elected to the Executive Committee may attend discussions and speak but may not vote nor be counted towards a quorum.

#### *MEMBERSHIP COMMITTEE*

- The initial Membership Committee will consist of the Chair of the Board of Directors, the Secretary, and two other Directors elected by the Board of Directors.
- The two non-Executive Officer positions on the Membership Committee will be elected from among the Board of Directors on a biennial basis. A term may be renewed once.
- The role of the Committee is to implement the above rules related to Group and Site Membership within the HNCIG and Partnerships with the HNCIG.
- The Membership Committee will develop and formalize, in collaboration with the Board of Directors, a review process for the application of new candidate Groups, Sites and Partners. The Membership Committee will also monitor the participation of members in HNCIG activities.

#### *HARMONIZATION COMMITTEE*

The remit of the Harmonization Committee is to advance international standardization related to Head and Neck Cancer.

#### *TRANSLATIONAL RESEARCH COMMITTEE*

The remit of the Harmonization Committee is to promote international collaboration in translational research on Head and Neck Cancers.

#### *LOCOREGIONALLY ADVANCED DISEASE COMMITTEE*

The remit of the locoregionally advanced disease committee is to promote international collaboration related to locoregionally advanced disease

#### *RECURRENT/METASTATIC DISEASE COMMITTEE*

The remit of the recurrent/metastatic disease committee is to promote international collaboration related to recurrent or metastatic disease.

## 8. MEETINGS

### *BOARD OF DIRECTORS MEETINGS*

Meetings of the Board of Directors will take place at least twice per year.

Meeting time, location, and agenda should be distributed to Directors at least a month before the meeting.

### *GENERAL ASSEMBLY*

Meetings of General Delegates will take place at least twice a year.

Meeting time, location, and agenda should be distributed to General Delegates at least a month before the meeting.

It may be convenient to hold Board of Directors meetings in conjunction with General Assembly meetings, but if so, General Delegates who are not also Members of the Board of Directors or otherwise officially invited to the Board Meeting should not attend the Board portion of the meeting.

## 9. SECRETARIAT

The Board of Directors may agree to work with an external organization that can provide administrative and support functions to facilitate work of the HNCIG. Such an organization could for example, provide support staff for record keeping, data storage, and support of the HNCIG website and databases. Revenue from dues and fees may be used to offset secretariat expenses with approval of the Board of Directors.

## 10. DUES AND FEES

The initial membership dues for Groups and Sites will be due on June 30, 2017. The initial fees for commercial partners will be due on the same date. Yearly dues and fees will continue to be assessed on June 30 in subsequent years. The dues and fees will be set by the Board of Directors.

## 11. STATUTES

Proposed amendments to these statutes must be delivered to the Secretariat no less than thirty (30) days prior to meetings.

Changes to these statutes require a majority vote and can only be made after circulating in writing to all members at least ten (10) days before the next scheduled Board meeting.

## ANNEX A: FOUNDING MEMBERS

CRUK (partner)

DAHANCA

ECOG-ACRIN

EORTC

Fudan University

German H&N Study Group

GORTEC

HeCOG (Hellenic Cooperative Oncology Group)

ICORG – Irish Clinical Oncology Group

Institute Gustave Roussy

IGR Meta-Analysis Group (partner)

Italian H&N Group

JCOG

Canadian Cancer Trials Group (formerly NCIC-CTG)

NRG Oncology

NCRI UK

NWHHT (Dutch H&N)

TCOG (Taiwan)

Tata Memorial Centre

TROG