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Gynecologic Cancer InterGroup (GCIG)

GOVERNANCE -- Standard Operating Principles (SOP)

The Gynecologic Cancer InterGroup (GCIG) is a collaborative group conceived in 1993 and formalized in 1997 with agreed upon Statutes/SOPs. It is a collaborative network consisting of appointed representatives from international and national research groups performing clinical trials in gynecologic cancers. The GCIG acquired non-profit incorporation status in May 2011.
This group has been very effective and has a history of successful collaboration and completion of randomized phase III trials, consensus conferences, brainstorming (state-of-the-art) initiatives, publications and reviews. International participation in trials has enabled achievement of rapid recruitment and international credibility for the results. The GCIG currently comprises a cooperative of full and provisional Members (groups), Governmental Authorities representation (Appendix A), Industry Partners (Appendix A), Observers and Liaisons. The Membership Meeting (General Assembly) may exceed two hundred (200) representative attendees. Meetings are held twice per year and include Standing Committees, Working Groups, the Board of Directors (Board) (+/- Executive Committee and Executive Officers) and Membership (General Assembly). In addition, the Board and/or Executive Officers and/or Executive Committee meet via teleconferences and/or email when necessary; and, subgroups of Committees/Working Groups utilize teleconferences and emails as required.

The key elements of success for the GCIG depend upon a set of common principles:

- Relationships between participants have been based upon mutual respect and equity for individuals, cultures and nations.
- The GCIG is unique amongst investigator groups and does not replicate any one existing mechanism but rather seeks to meet the needs of all Members.
- Intellectual contributions come from individual group members and the GCIG serves as a mechanism to advance these.
- The GCIG processes facilitate and support the intellectual contributions from member groups.

- There are a set of agreed upon Statutes to support the processes within the GCIG which are consistent-with and adjunct-to the Corporation's legal bylaws.

Statutes and Executive

The Statutes of the GCIG inform governance of the activities of the GCIG and are attached to this document.

The formal leadership of the GCIG is the Board of Directors (Board) led by the Chair-elect, the Chair and the past Chair. An election is held by the Board at the "Spring" meeting every two years to identify, by vote, the Member (group) which will provide the Chair-Elect. The Chair-Elect is then identified by the elected Member (group) to take the role of Chair-Elect as of the following "Autumn" meeting. The Chair is elected for one-year as Chair-elect, two years as Chair and two years as past-Chair. The Chair acts as the official spokesperson of GCIG.

The Board includes:

1) the Executive Officers (Chair-Elect, Chair, past-Chair and Secretary-Treasurer);
2) the Executive Committee (Executive Officers, Chair Membership, Chair CCRN, and such other Directors as appointed by the Board);
3) one voting Director from each Member (group) (re-elected by member group and re-consented [doc] annually);
4) non-Member Directors at its discretion.

Committees and Working Groups

The Standing Committees are defined in the Statutes and Bylaws. The Committees and Working Groups are the collective intellectual vehicle of the GCIG where ideas from individual member groups are brought for further discussion by the Committee/Working Group before coming before the Board and/or Membership (General Assembly). There are currently ten (10) Standing Committees embedded in the Statutes. Any number of additional working groups may be formed by the Board on an ad hoc basis. The number of these additional Working Groups is to be kept to a minimum with clear tasks and guidelines enunciated by the Board. Their composition and function will be reviewed regularly by the Board.
Each of these Committees and Working Groups will have a Chair and Co-Chair [nominated by the Members and selected/appointed by the GCIG Chair on the advice of the Board] who prepares the agenda ahead of time and is responsible for ensuring an adequate record, and reports to the Board and/or Membership (General Assembly). The Chair is usually appointed for a two-year term subject to one renewal so as to ensure sustainability of the groups as appropriate.
(Appendix C: Terms of Reference)

Those serving in the Committees/Working Groups should have **expertise and responsibility relevant to that working group, as well as a commitment** to attend and participate. Committees/Working Groups consider proposals brought forward by Members (groups), seek opportunities for international collaboration with established trials, and identify gaps which may be filled more effectively through international collaboration rather than individual Members (groups).
These Committee/Working Group meetings are critical to the effectiveness of GCIG and need adequate preparation and time, considering the effort and expense involved in convening twice yearly meetings. Effective discussion at the Working Groups should enable the Membership meeting (General Assembly) to be conducted more efficiently.

The ten (10) standing Committees of the GCIG are :

- Membership Committee
- Harmonization Committee (Operations & Statistics)
- Translational Research Committee
- Ovarian Cancer Committee (Early, IP, Advanced & Recurrent)
- Cervix Cancer Committee (+ vagina, vulva)
- Endometrial Cancer Committee (+ GTD)
- Rare Tumours Committee
- Symptom Benefit Committee
- Phase II Committee
- Cervix Cancer Research Network (CCRN)

Additionally, there are currently five (5) active Working Groups.

- Megadatabase – Steering & Working Group
- Quality Assurance (QA) – Steering & Working Group
- Education – Steering & Working Group
- Consensus Conference – Scientific & Planning Group
- Brainstorming (state-of-the-art) – Scientific & Planning Group

The mandate of Committees/Working Groups:

- Committees/Working Groups will nurture new trial-related concepts addressing major questions in their domains brought forward by Members (groups) and then make a recommendation to the Board and/or Membership for their support.
- Committees/Working Group meetings are open meetings but attendees must be pre-registered with the Operations Manager at least four (4) weeks in advance of the meeting.
- The Chair will present a summary on behalf of the Committee/Working Group to the Board and/or Membership (General Assembly) for discussion.

Protocol Development and Participation

Electing to participate as a group in protocol development from a concept that has been brought forward by a Committee/Working Group and approved by the Board is a voluntary decision. However, once a Member (group) has elected to participate in the protocol development of a specific trial it is expected that the Member (group) would then participate in accrual to that trial. It is recognized that there may be extenuating circumstances that affect this principle but this should be unusual. The development of a formal protocol from an approved concept will be conducted by a Steering Group which usually consists of at least one representative from each participating Member (group) and will be chaired by the Study Chair (usually the person submitting the original concept). The final protocol will be approved by a majority vote of the Steering Group. All issues related to the execution, analysis and authorship will be decided in advance of protocol activation.

The Board will have oversight of the process by which Committees/Working Groups decide which areas of interest need to be addressed by intergroup studies. From time to time, the Board may need to request that a Committee/Working Group address specific needs when deemed necessary.

None of these proposals should interfere with any individual Member's (group's) right to autonomy. A Member's (group's) participation in any protocol is voluntary. However, the principle exists that contributing and shaping the intellectual content of a protocol is usually associated with active participation in that protocol.

Publication guidelines would be determined and agreed upon at the outset of any GCIG protocol. Additional principles are enunciated in the attached "GCIG Authorship Policy". (Appendix B).

Frequency and Timing of Meetings

The process of achieving InterGroup collaboration requires effective interaction and benefits from regular interaction. Although expensive and time consuming, twice yearly meetings are desirable and necessary. Teleconferences are valuable for additional timely discussion on specific issues.

Ideally, venues should facilitate optimal participation and representation (although ASCO as a fixed event, and IGCS, ECCO and ESGO, offer opportunities to combine GCIG with international meetings) with ease of international travel access.

The format of the meetings extends over a two-day period. This allows for meetings of brainstorming (state-of-the-art) sessions and the Standing Committees and Working Groups. Although it is desirable to minimize the number of concurrent meetings, there will be overlap as Committees/Working Groups need to have adequate time available for effective deliberations. Not to overlap with these meetings, the Board will meet separately for the conduct of business.

The second day will include the meeting of the Membership (General Assembly). This would include:

- an opportunity for update from each group and industry partners present;
- an opportunity for any new business;
- a summary provided from each Committee and Working Group (including ongoing trials or new concepts).

The format will facilitate open participation and remain as a forum for sharing ideas and seeking new collaborations. It is anticipated that much of the detailed scientific discussion would take place in the Committees/Working Groups.
Following the Membership Meeting (General Assembly), the Board will meet in order to confirm further action steps prior to the next meeting and/or decide on protocols and initiatives to be endorsed.

Professional Administration

Administration of the GCIG is provided by three (3) roles within the **Secretariat**. This shared Secretariat role reflects the activity and complexity of the GCIG:

The **webmaster** services continue to be generously provided without direct cost to the GCIG by NCI (US) in lieu of dues. This is through the NCI's contracted services of Emmes Corporation [@emmes.com]. [activity equal to 0.2 FTE (full time equivalent)]

Strategic planning, **secretary-treasurer tasks and operations management** are contracted by GCIG with Monica Bacon and Katherine Bennett.[combined activity equal to 0.6 – 0.8 FTE (full time equivalent)]

Book-keeping services are contracted by GCIG with Charlan Tryan at $20. CAD/hour.

May 2016

GYNECOLOGIC CANCER INTERGROUP (GCIG)
STATUTES (SOPs)

1. Definition

The Gynecologic Cancer InterGroup (GCIG) is an organization comprised of appointed representatives from international and national member research groups performing clinical trials in gynecological cancer.

2. Aims:

- Promote international collaboration.
- Promote clinical research.
- Perform studies in females with rare tumors.
- Stimulate evidence-based medicine by performing high quality clinical trials.
- Support educational activities (mainly by disseminating results of GCIG trials).

3. Membership and Attendance:

- Any international or national research group performing clinical trials in gynecological cancer may apply to become a Member (group) of the GCIG. A potential new member group should express their interest to join the GCIG by completing the Membership Application form and submitting it to the Membership Committee via the Operations Manager. The group may send one **observer** representative to GCIG open meetings; repeat attendance is decided by the Exec **Officers.** Thereafter they need to apply for Membership.

- A Provisional or Full **Member** (group) of the GCIG may appoint up-to 6 authorized representatives to attend GCIG meetings;
    - principal representatives (investigators), statistician, data manager/operations expert, translational researcher, pathologist, etc. The **Member** (group) selects its attendees/representatives and is responsible for coverage of sub-specialties. Once per calendar year, a statistician &/or data

manager/operations representative must attend. Attendance by Chairs of Committees & Working Groups is exempt from the Member's allotted six (6).

- A **Member** (group) shall pay dues to the GCIG on a yearly invoiced basis. The yearly dues will be decided upon by the Board.
- The **Member** (group) is responsible for informing updates of authorized representatives to Operations and Webmaster (Roster and specified Committee/Working Group appointments).
- The **Member** (group) is responsible for informing Operations and Webmaster of other than "authorized representatives" appointed to serve as "distant" expert liaisons to Committees/Working Groups.

- **Government/National Regulatory Authorities Members** : GCIG member groups may recommend Government/National Regulatory Authorities partners. If approved by the Membership Committee, the national head office of that Authority will receive an invitation from the GCIG Chair to join GCIG and send up-to six (6) representatives to GCIG meetings and social events. In the event of real and/or perceived conflict of interest, these partners should recuse themselves **at the request of the Chair**. Annual dues will be determined by the Board and paid when invoiced by the Operations Manager.

- **Liaisons:** other international organizations with same or similar goals, may request of Executive Officers (via Operations) the privilege/courtesy of one (1) representative attending GCIG open meetings as a non-voting observer and collaborating participant (eg: ENGOT, IGCS, BIG, ISSTD, WSN, TACT, H&NIG, etc).

- **Industry Partners** Program: GCIG member groups may recommend Biotech/Pharma partners. If approved by the Membership Committee & Executive Committee, and acceptance is recommended to the Board and therein approved, the international head office of the industry partner will receive an invitation from the GCIG Chair to join GCIG and send up-to two non-voting representatives to open meetings (Standing Committees, Working Groups and General Assembly) and social events. In the event of real and/or perceived conflict of interest, these partners should recuse themselves **at the request of the Chair**. Annual dues will be determined by the Board and invoiced by the Secretariat.

- **Invited Guests:** In the event that a Committee/Working Group, the Board, the Membership (General Assembly) is unable to identify a necessary expertise from within the GCIG Members, a request may be sent via Operations to the GCIG Chair for permission to invite an outside expert Speaker for that (and only that) session/meeting. This Speaker will also be invited to join the usual GCIG Dinner (gratis) by Operations.

4.a GCIG Executive Officers:

The GCIG Executive Officers are the Chair, Chair-elect, Past Chair, and Secretary, Treasurer. (see GCIG bylaws).

4.b GCIG Executive Committee:

The Board may elect an Executive Committee of no-less-than three (3) members composed of the Executive Officers, the Membership Chair, the CCRN Chair, and other Directors as appointed/resolved/minuted by the Board. During the intervals between the meetings of the Board, 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 **(for example: approve or reject requests for endorsements).** Directors not elected to the Executive Committee may attend discussions and speak but may not vote nor be counted towards a quorum.

5. Board of Directors::

- The GCIG is led by a Board of Directors consisting of the Executive Committee , a voting Director representative of each Member (group) and non-member Directors appointed by the Board.
- The Board has the power to make decisions concerning all business matters provided that a quorum of Directors are present. The GCIG Chair has a casting vote in case of a tie.
- Each Member (group) will have one vote on the Board.
- Changes to GCIG **statutes/SOPs** 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.
- In the absence of a Director at a Board meeting, the respective Director (Member group) may appoint a substitute/proxy.
- The Chair will review/approve materials (**SOPs, governing** concepts, etc.) prior to broad distribution by the Secretariat personnel.
- Proposed amendments to the GCIG corporation **bylaws** must be delivered to head office (operations manager) no less than thirty (30) days prior to meetings and subsequent notification provided to members (groups) no less than ten (10) days prior to meetings.

6. GCIG Chair:

- Criteria of Chair :
    - Commitment to GCIG including
        - Intergroup studies activity
        - Attendance and participation in GCIG meetings
        - Active participation (e.g. committees/working groups)
- Election of Chair:
    - The Chair will rotate among Members (groups).
    - The term of the Chair will be five years; one year as Chair Elect, two years as Chair and two years as Past Chair.
    - The new Chair elect Member (group) will be appointed by the majority vote of the Directors entitled to vote at the Board meeting preceding the commencement of new term of office. The elected Member (group) will appoint the individual to serve as Chair elect.
    - Nominations for Chair elect will be presented to all members before being

confirmed.

- Roles of Chair
  - GCIG Chair
    - Chair Membership meetings (General Assembly)
    - Chair the Board of Directors (+ Executive Committee + Executive Officers)
    - Act as official spokesperson of GCIG
    - Approve expenditures
    - Assure corporation bylaws observed/followed
    - **In collaboration with the relevant Committee/Working Group Chair, approve or reject requested distribution of materials (eg. surveys)**
    - Oversee Secretariat personnel/activities

7. GCIG Secretariat

- Contracting of Secretariat personnel occurs by consensus of the Board.
- Roles of Secretariat:
  - Operations Manager(s) [Officer of GCIG] (see GCIG contracts)
    - Organize meetings and functions of GCIG
    - Assist Chair, Executive and Board in observance of corporation bylaws
    - Maintain collaborative communications and activities
    - Respond to requirements of Chairs (of the Board, Standing Committees and Working Groups).
    - Coordinate interactions between members and the Executive & the Board (e.g. endorsement requests).
    - Manage membership applications and recommendations.
    - Conduct business for GCIG with service providers (lawyer, accountant, auditor, banking, investments/securities, insurance, teleconferencing, revenue Canada, Industry Canada, etc)
    - At the behest/appointment by the Board, perform standard secretary – treasurer functions (including invoicing member groups and partner members for annual dues, reimburse approved expenditures, maintain financial accounts, report on accounts to Board – in collaboration with Book-keeper). (Including Minutes, correspondence, etc.)
    - Collaborate with webmaster.

  - Webmaster
    - Contracted by NCI US to develop, maintain and update GCIG website (report at GCIG meetings)
    - Disseminate materials as directed by the Board and Executive Committee via Operations.
    - Maintain GCIG roster
    - Assist with editing GCIG documents and manuscripts.
    - Facilitates Q & A activity (including collecting “outcomes”).
    - Collaborate with Operations Manager.

  - Book-Keeper
    Contracted by GCIG, to supervise and control the financial business of GCIG in collaboration-with and under supervision-of Operations

8. Membership and Meetings:

- Meetings of the Board and the Membership (General Assembly) will take place twice annually or at any other time determined upon by the Board.
- Committee/Working Group Chairs will be invited to attend one Board meeting per annum as non-voting participants.

9. Committee Structure

The GCIG includes ten (10) standing Committees as per Governance/SOPs and Bylaws.

The GCIG includes Working Groups as determined by the Board (for example: Response/Progression, FIGO, Classifications, Screening, Sentinel Nodes, Intraperitoneal Therapy, Megadatabase, Education, QA, etc.) and currently as per Governance/SOPs and Bylaws.

10. GCIG trials and activities:

- Definition of GCIG trials
  - GCIG trials are those gynecologic cancer trials involving any two or more GCIG Members (groups).
- GCIG logo
  - The GCIG logo will be inserted on the front page of GCIG protocols.
  - The GCIG logo may not be used in publications of non GCIG trials or activities without the permission of the GCIG Board.
  - **The GCIG logo will be included on (at least the title) slide of GCIG presentations.**
- GCIG trials
  - One of the collaborating groups in a GCIG trial will be appointed as leading group (determined by the collaborating groups)
  - The leading group of a GCIG trial will provide the Secretariat with information concerning title, status, participating groups, contact information.
  - A list of GCIG trials will be published on the GCIG website.
- GCIG bibliography
  - A list of published GCIG trials or other GCIG publications will be posted on the GCIG website.
- Other GCIG activities
  - Publications resulting from GCIG activity (e.g Working Groups) will be published "on behalf of GCIG". Members of the working groups or Special Projects team will be co-authors unless otherwise decided upon by the group.
  - Authorship will be agreed upon prior to trial/project commencement.
  - Only when manuscripts have been approved by the Working Group members, and reviewed by the GCIG Chair can they be submitted for publication.

APPENDIX A
May 2016

GCIG Industry Partners Program (IPP)

Individual GCIG member groups and the GCIG as a whole, noted ongoing difficulties in establishing collaborative development with the pharmaceutical and biotechnology industry. In the absence of an ongoing relationship with industry, it was difficult for GCIG to incorporate the most promising new agents in trials. In addition, in the absence of governmental support for infrastructure for clinical trials, GCIG member groups must ask industry for central support and additional per capita funds for accrual. In some instances, companies with new agents may be unwilling or unable to underwrite the trial even if they are willing to supply the drug. This Industry Partners Program (IPP) strengthens the GCIG by establishing mechanisms for formal liaisons with industry.

At the recommendation of the GCIG Board, GCIG established a "GCIG IPP ".
Companies are recommended by Members and then, if accepted, invited by the Chair to join the IPP and send up-to two representatives to attend the open meetings of the GCIG Standing Committees, Working Groups and general assembly. Should the Chair of these meetings feel that presence of industry representatives might preclude frank discussion of a particular issue or trial, then s/he has the right to ask industry representatives to leave the meeting for as long as that item is being discussed. In addition, the industry representatives would be invited to attend the GCIG social evening.
Companies are invoiced to pay dues to join, which helps to support the work of the GCIG. Annual dues are determined by the Board and invoiced by Operations/Secretariat. At the end of one year (after two GCIG semi-annual meetings with participation from industry), the GCIG Industry Partner will be evaluated by the GCIG Board and Membership Committee at which time the Partner's participation will be terminated, modified, or continued based on the assessment.

This outreach to industry heightens awareness within the pharmaceutical/ biotechnology community of the GCIG, its member groups, and the urgent need for new agents in the treatment of gynecologic cancer.

Government/National Regulatory Authority Partners

At present, the National Cancer Institute (USA) is a member organization of GCIG, although it is somewhat anomalous, being a $ponsor of American GCIG Members (NRG [GOG and RTOG], ACRIN, G-GOC, COGi) and partial $upporter for the data centers of NCIC CTG, PMHC and EORTC GCG.

This membership category is termed "Government/National Regulatory Authority Partners" for governmental organizations or non-governmental organizations which provide support to one or more GCIG member groups.
Each partner is entitled to send representatives to the GCIG Standing Committees, Working Groups, general assembly and social functions.
This category of membership encourages governments/NGOs to support clinical trials infrastructure and heighten public awareness of gynecologic cancer trials. In addition, this category regularizes the position of NCI (USA) within the GCIG.

Annual dues for these partners are determined by the Board and invoiced by Operations/Secretariat.

APPENDIX B
May 2016

Authorship Policy

Principles

Authorship is to be established at the outset of any GCIG trial/project/initiative.

- Publications on behalf of the GCIG may be clinical trials reports, survey results, consensus statements, descriptive manuscripts or any other intellectual contribution in the scientific media including print, electronic media or both.
- GCIG should be acknowledged in any publication emanating from the GCIG process.
- This acknowledgement would usually be in the title (e.g. “A study of the GCIG”; “a GCIG study”; “on behalf of the GCIG” etc).
- The lead author should be that person responsible for the major intellectual contribution of the manuscript. (This person would usually be either a Study Chair or a designated member of the GCIG on behalf of one of the Working Groups or Board, but should always be approved by the relevant Member [group].)
- Names and ordering of additional specific authors should be approved by the Members (groups) participating in the study.
- Institutional designation of the author is to be consistent with the Member (group) guidelines.
- Post-publication copies of such documents will be available on the GCIG website
- Authorship and publication plans will be determined and agreed upon at the outset of all GCIG clinical trials and/or initiatives.
- Final manuscripts should acknowledge all participant Members (groups).