

**GYNECOLOGIC ONCOLOGY GROUP**

**MEMBERSHIP COMMITTEE**

**STANDARDS FOR EVALUATION FOR MEMBERSHIP**



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**1.0 TYPES OF MEMBERSHIP**

**1.1 Provisional Member**

This category of membership is reserved for institutions as an initial means of entry into the Gynecologic Oncology Group (GOG) to allow time for the Membership Committee to evaluate the performance of the institution. Each Provisional Member is expected to meet the standard for Full Membership within two years. Provisional Members may have representatives who serve on the various Committees of the Group, except the Board of Directors and the Membership Committee. Representatives of Provisional Members may not hold office and may not vote except in matters involving protocol approval.

**1.2 Full Member**

Full Member Institutions will be voting members of the GOG. Representatives of Full Members may serve as officers, members of the Board of Directors, and members of other committees. A Full Member will generally play an active role in a number of study programs, group protocols and actively participate in group meetings.

**1.3 Affiliate Member**

GOG Full Members may choose to have Affiliate Members. Affiliates are institutions who, either by choice or circumstance, cannot meet Full Membership requirements but want to participate in GOG activities and protocols. These institutions can participate by becoming an Affiliate of a Full Member institution. International Institutions may become an affiliate of a institution which is located within the United States. The Affiliate can enter patients onto protocols through a Full Member. Affiliate status allows institutions to gain experience with the GOG. Affiliate status may be sought by institutions that are not accepted for GOG Provisional Membership or by institutions without adequate accrual to meet Full Membership standards.

## 1.4 International Member

International Member Institutions will consist of Institutions whose primary site is outside of the United States and its Territories. These institutions may be comprised of a Clinical Trials Cooperative Group which wants to maintain active, ongoing participation in the GOG.

- 1.4.1 An International Member will generally play an active role in a number of study programs, group protocols and actively participate in the group's meetings. A representative must attend at least one meeting a year but others are encouraged to attend.
- 1.4.2 An International Member must have at least one Phase III Protocol open at all times, if an appropriate protocol is available which the Member is able to open. They must put at least 6 patients on a Phase III protocol each year.
- 1.4.3 An International Member will not be a voting member of the GOG, unless they meet the Full Membership Standards as detailed in section 3.3.
- 1.4.4 International Member personnel may become members of GOG committees. They may not serve as officers or as members of the Board of Directors except as an ex-officio member.
- 1.4.5 International Members may accept Affiliate Members when approved by the Membership Committee and the Board of Directors. They must meet all the standards of a Full Member with respect to Eligibility, Evaluability and Completeness of Records before they can accept an Affiliate.

## 1.5 Gynecologic Cancer Intergroup (GCIC) Members

The GCIC is an Association of 18 International Cooperative Groups. Each Group within the GCIC may become a Provisional and eventually a Full member of the GOG.

- 1.5.1 The GCIC Members will generally play an active role in a number of study programs, group protocols and actively participate in the GOG meetings. At least one representative must attend at least one meeting a year but others are encouraged to attend. If a Group within the GCIC is a Full or Provisional member of the GOG, one of the attendees must be from that Group.

- 1.5.2 The Group Member must have at least one Phase III Protocol open at all times and must put at least 6 patients on a Phase III protocol each year if an appropriate trial is available.
- 1.5.3 The GCIG Group Members will not be a voting member of the GOG unless they become a Full Member and are in good standing.
- 1.5.4 GCIG Member personnel may become members of GOG committees. The members may not serve as officers. At the discretion of the Board of Directors one member of the GCIG may have a seat on the Board of Directors as a voting member or an ex-officio member.
- 1.5.5 The GCIG Group Member will undergo Audits per NCI Standards.

## 1.6 **Community Clinical Oncology Program (CCOP) Members**

CCOP and MBCCOP are groups of community hospitals and physicians funded by a peer-reviewed cooperative agreement to participate in NCI-sponsored cancer treatment, prevention, and control clinical trials. MBCCOPs generally attribute at least 40% of their newly diagnosed cancer patients from minority populations. CCOP institutions are not voting members of GOG, but have a limited vote in GOG matters, as provided in Section 6.0.

## 1.7 **CTSU Institutions**

Institutions enrolling patients to GOG studies through the Clinical Trials Support Unit (CTSU) must be either a member of another Cooperative Group, or part of the CTSU Independent Clinical Research Site (CICRS) program. They are not voting members of GOG. GOG member institutions cannot enroll patients through GOG and CTSU during the same timeframe.

## 2.0 EVALUATION OF PROVISIONAL MEMBERSHIP

### 2.1 Evaluation of Provisional Membership Applications

A Full Member that was terminated cannot apply as a Provisional Member for two years. By the time of reapplication the reason(s) for termination must have been remediated.

An Affiliate Member that was terminated for not meeting the accrual requirements cannot apply for Provisional Membership for two years.

2.1.1 **Patient Caseload:** Provisional Member applicants must care for a minimum of 150 new invasive gynecologic malignancy cases per year. Of these 150 cases, 100 must be primary untreated cases. The remaining 50 may be previously treated cases.

2.1.2 **Multi-Disciplinary Requirements:** The GOG is a multi-disciplinary group, and multi-disciplinary representation should be included in each application. Each application for Provisional Membership must have a Gynecologic Oncologist, preferably Board Certified, and a Pathologist as participating members of the team. Medical Oncology and/or Radiation Oncology must also be represented on the institutional team. Preferably, both disciplines should be represented. Letters of intent from a representative of each discipline must accompany the application.

2.1.3 **Institutional support:** The CEO or Director of Research at the proposed Principal Investigator's (PI) institution must submit a letter in support of the application. This letter must include a statement regarding financial support. This letter must indicate an Institution's commitment to continue the submission of follow-up data on patients entered on protocol, even in the event the proposed PI leaves the institution.

2.1.4 **Previous GOG Experience:** The GOG Administrative Office and Statistical Data Center will supply the Membership Committee with data outlining the proposed Provisional Member Institution's previous GOG participation, if any. This will include accrual data, a review of completeness, eligibility, evaluability, and reports of previous audits and data assistance reviews.

2.1.5 **Deadline for Provisional Membership Application:** The completed Provisional Membership Application must be returned to the GOG Administrative Office **45 days** prior to a Semi-Annual Meeting to be considered at that meeting. A completed application includes an Invasive Gynecologic Malignancy Form signed by the PI, a completed questionnaire, a letter of support from the Institution's CEO or

Director of Research, and letters of support from a representative of each discipline that will participate in GOG protocols and activities.

2.1.6 The PI from the applicant institution should attend the Semi-Annual Meeting at which the application will be reviewed. The Membership Committee may request that the PI attend the Membership Committee Meeting during which the application is considered.

2.1.7 **Granting Provisional Membership:** Provisional Membership may be granted at a Semi-Annual Meeting, on the recommendation of the Membership Committee and with the approval of the Board of Directors.

## 2.2 **Application for change in status from Affiliate to Provisional**

2.2.1 An Affiliate institution which has demonstrated satisfactory performance as an Affiliate may apply for and be granted Provisional Membership. The Affiliate must meet all requirements for Provisional Membership (Section 4.0), including patient accrual, protocol participation, meeting attendance, multi-disciplinary representation and institutional support. In addition, any cases entered as an Affiliate must meet the Provisional Membership requirements for points, eligibility, and completeness of records.

2.2.2 The decision to change the status of an Affiliate to Provisional Membership shall be made by the Membership Committee and approved by the Board of Directors. This shall be a judgment based on the application and the participation history of the institution.

2.2.3 An affiliate that desires a change in status to Provisional Member must submit an application in writing to the Membership Committee. A letter of acknowledgement from the current sponsoring Full Member institution must also be submitted to the GOG Administrative Office. These materials must be received by the GOG Administrative Office **45 days** before the next scheduled Semi-Annual Meeting to be considered at the meeting.

## 2.3 **Membership Standards for continuing Provisional Membership**

2.3.1 **Timing of Review:** Provisional Member evaluation will take place at least semi-annually.

2.3.2 **Protocol Participation:** Provisional Members must participate in protocols such that a minimum of 100 High Priority Points and 150 total points are accrued per year. High Priority Protocols are those which award at least 6 membership points per patient.

- 2.3.3 **Eligibility and Evaluability:** Ninety percent (90%) of all cases entered must be eligible and ninety percent (90%) of all eligible cases must be evaluable.
- 2.3.4 **Completeness of Data:** Eighty-five percent (85%) of all records must be complete at all times and eighty-five percent (85%) of follow-up forms must be complete.
- 2.3.5 **Meeting Attendance:** A minimum of one representative of the Provisional Member must attend each Semi-Annual GOG Meeting.
- 2.3.6 **Multi-disciplinary Requirements:** Each Provisional Member must have a full time Gynecologic Oncologist and a Pathologist. A Medical Oncologist and/or Radiation Oncologist should be represented on the institutional team. Participation by all four disciplines is preferable.
- 2.3.7 **Audits:** The Provisional Member should be audited within 12-18 months after the first patient entry. The Audit Committee will supply the Membership Committee with a report of any recent audit of any Provisional Member institution. These reports will be used in the evaluation of Provisional Members. An unacceptable audit report will adversely affect the Provisional Member's status and may prevent the institution from attaining Full Membership. Repeated unacceptable audits may lead to termination.

### 3.0 EVALUATION OF FULL MEMBERSHIP

#### 3.1 Evaluation of Full Membership Applications

- 3.1.1 **Bypassing Provisional Membership:** The process of bypassing Provisional Membership is generally reserved for single established institutions with established PIs.

#### 3.2 Evaluation of Application for change from Affiliate to Full Member

- 3.2.1 **Satisfactory Performance:** An affiliate that has demonstrated satisfactory performance as an Affiliate Member may apply for Full Membership and it may not be necessary for this institution to spend time as a Provisional Member. The affiliate must have met all the requirements for Full Membership (Section 5.0), including patient accrual, protocol participation, meeting attendance, multi-disciplinary representation and institutional support. In addition, any cases entered as an Affiliate must have met the Full Membership requirements for points, eligibility, evaluability and completeness of records.
- 3.2.2 **Decision to change status:** The decision to change the status of an Affiliate to Full Membership shall be made by the Membership Committee and approved by the Board of Directors. This shall be a

judgment based on the application and the participation history of the institution.

- 3.2.3 **Submission of Provisional Membership Application:** An affiliate that desires a change in status to Full Member must submit an application in writing to the Membership Committee. A letter of acknowledgment from the current sponsoring Full Member institution must also be submitted to the GOG Administrative Office. These materials must be received by the GOG Administrative Office **45 days** before the next scheduled Semi-Annual Meeting to be considered at that meeting.

### 3.3 **Membership Standards for Continuing Full Membership**

A Full Member institution is expected to be able to meet membership requirements on its own and should not have to rely on cases entered from its affiliates to maintain Full Membership.

- 3.3.1 **Timing of Review:** Evaluation of Full Members will take place at least semi-annually. At that time, the performance of the Full Member, as well as all of its affiliates, will be reviewed jointly. An unacceptable review may lead to probation (see Section 6.0).
- 3.3.2 **Protocol Participation:** Full Members must participate in GOG protocols such that a minimum of 100 High Priority Points (see Section 4.2) and 150 total points are accrued per year. Seventy-five points should be accrued by the mid-year meeting.
- 3.3.3 **Eligibility and Evaluability:** Ninety percent (90%) of all cases entered must be eligible and ninety percent (90%) of all eligible cases must be evaluable.
- 3.3.4 **Completeness of Data:** Eighty-five percent (85%) of all records must be complete at all times and eighty-five percent (85 %) of follow-up forms must be complete.
- 3.3.5 **Meeting Attendance:** A minimum of one representative of the Full Member must attend each Semi-Annual Meeting. This individual should be authorized to vote. Each Full Member has only one vote.
- 3.3.6 **Multi-disciplinary Requirements:** Each Full Member should have a full-time Gynecologic Oncologist and a Pathologist. A Medical Oncologist and/or Radiation Oncologist should be represented on the institutional team. Participation by all four disciplines is preferable.
- 3.3.7 **Audits:** The Audit Committee will supply the Membership Committee with a report of any recent audit of any Full Member institution and a report on any of its affiliate audits. These reports will

be used in the evaluation of the Full Member institution. An unacceptable audit report on a Full Member institution or any of its affiliates may lead to probation. Repeated unacceptable audits will likely lead to termination.

#### 4.0 EVALUATION OF AFFILIATE MEMBERSHIP

- 4.1 **Evaluation of Affiliate Membership Applications:** An Affiliate Institution that was terminated for not meeting the standard requirements cannot reapply for affiliate membership for two years. To reapply, the Full Member Institution and the proposed affiliate should submit a written plan describing how the proposed affiliate will meet its standard requirements. Representatives of the Full Member Institution and the proposed affiliate may be requested to attend the Membership Committee Meeting.

The Full Member institution will be responsible for each of its affiliates. The Full Member must have a written agreement with each of its Affiliates that assures that the Affiliate will be bound by the contractual obligations between the Full Member and GOG. Most important, the Full Member institution will be responsible for the quality of participation by the affiliate. The Full Member institution's plans for monitoring its proposed affiliate must comply with the NCI's CTMB Auditing Guidelines. The logistics of the affiliation will be reviewed in detail. Any delinquency, ineligible patient, and/or inevaluable patient that the affiliate has will be counted against the Full Member.

- 4.1.1 **Patient Caseload:** The proposed Full Member institution must supply the Membership Committee with projections of the proposed affiliate's accrual.
- 4.1.2 **Multi-disciplinary Representation:** The proposed Affiliate Institution must have participation by a Pathologist and at least one of the following disciplines: Gynecologic Oncology, Medical Oncology and/or Radiation Oncology. Letters of intent from a representative of each discipline must accompany the application. The Affiliate institution must name a person to serve as the Responsible Investigator for that institution.
- 4.1.3 **Institutional Support:** The CEO or Director of Research of the proposed Affiliate Institution and the PI must submit a letter approving and supporting the institution's affiliation and participation. **If the proposed affiliate is a private practice group, this letter must be from the CEO/President of the private practice corporation.** This letter must indicate that the CEO/Director of Research will be responsible for the continued submission of data should the proposed Responsible Investigator leave or the affiliation be terminated. It is the responsibility of the sponsoring Full Member institution to see that these requirements are met and documentation is supplied to the

Membership Committee. The CEO or Director of Research of the sponsoring Full Member institution must also submit a letter, on institutional letterhead, indicating support for the addition of an affiliate.

- 4.1.4 **Previous GOG Experience:** An Affiliate Institution that was terminated for not meeting the standard requirements cannot reapply for affiliate membership for two years. The GOG Administrative Office and Statistical Data Center will supply the Membership Committee with data outlining the proposed Affiliate Member institution's previous GOG participation, if any. This will include accrual data, a review of completeness, eligibility, evaluability, and reports of previous audits and data assistance reviews.
- 4.1.5 **Deadline for Affiliate Application:** The completed application must be returned to the GOG Administrative Office **45 days** prior to the next Semi-Annual Meeting for consideration at that meeting. A completed application includes a completed questionnaire by both the Full Member institution and the Affiliate, a letter of support from the CEO or Director of Research of the proposed Affiliate, and letters of support from a representative of each discipline that will participate in GOG protocols and activities at the proposed Affiliate institution.
- An Affiliate application may be accepted by the Membership Committee but the new Affiliate may not be activated with the Sponsoring Full Member Institution if that institution is not in good standing at the time of the meeting. The newly approved Affiliate may consider affiliating with another Full Member Institution in good standing or wait six months until the next GOG Semi-Annual Meeting assuming the sponsoring institution is in good standing at that meeting. If the sponsoring institution is still unable to accept an affiliate, then the approved affiliate must select another institution within 2 weeks of the Semi-Annual meeting or reapply for affiliate status at the next Semi-Annual meeting.
- 4.1.6 The PI from the sponsoring Full Member Institution should attend the Semi-Annual Meeting at which the application will be reviewed. The Membership Committee may request that the PI attend the Membership Committee Meeting during which the application is considered.
- 4.1.7 **Granting Affiliate Membership:** Affiliate Membership may be granted at a Semi-Annual Meeting, on the recommendation of the Membership Committee and with the approval of the Board of Director.

- 4.2 **Membership Standards for Continuing Affiliate Membership:** The sponsoring Full Member institution and the proposed affiliate will be reviewed as one institution.
- 4.2.1 **Timing of Review:** Within **30** days of the January GOG Semi-Annual Meeting, the Statistical and Data Center will notify the Administrative Office of any Affiliate Member Institution that has not complied with the requirement of placing three (3) patients on Major GOG Protocols in the past year. The Administrative Office will notify the Principal Investigator of the Parent Institution that their Affiliate is to be discontinued. The Principal Investigator of the Parent Institution will have **30** days in which to appeal this decision to the Group Chair who, with the Membership Appeals Committee, will accept or deny the appeal. If the appeal is accepted, the Affiliate must place at least 1 patient on a **MAJOR** GOG Protocol before the summer meeting. Failure to do this will be an automatic discontinuation of membership, without appeal. Failure of the Affiliate to place at least three (3) patients on Major GOG Protocols within the year after the appeal will be an automatic discontinuation of membership. The Parent Institution will still be responsible for all the data of patients previously placed on a GOG Protocol.
- 4.2.2 **Protocol Participation:** The proposed affiliate should obtain approval from its IRB of GOG protocols as expeditiously as possible. It is the responsibility of the sponsoring Full Member Institution to assure IRB approvals. In order to continue membership in the GOG, each affiliate must enter a minimum of three (3) patients onto **MAJOR** GOG treatment protocols each year. Points awarded for protocol participation by an affiliate will be counted in the Full Member institution's total.
- 4.2.3 **Eligibility and Evaluability:** Ninety percent (90%) of all cases entered must be eligible and ninety percent (90%) of all eligible cases must be evaluable.
- 4.2.4 **Completeness of Data:** Eighty-five percent (85%) of all records must be complete at all times, and eighty-five percent (85%) of all follow-up records must be complete.
- 4.2.5 **Meeting Attendance:** Attendance by a representative of the Affiliate at each Semi-Annual Meeting is strongly encouraged.
- 4.2.6 **Multi-disciplinary Requirements:** Each Affiliate Member is required to have a Pathologist and representation from at least one of the following disciplines: Gynecologic Oncology, Medical Oncology, and/or Radiation Oncology. Participation by all four disciplines is preferable.

- 4.2.7 **Audits:** Affiliate institutions must be audited by their Full Member within 36 months of the first patient entry by the affiliate and no more than every 36 months thereafter. These audits must be on-site at the affiliate institutions. The Audit Committee will supply the Membership Committee with a report of any recent audits. An unacceptable affiliate audit may lead to probation for the Full Member institution. (Section 3.37)

## 5.0 INTERNATIONAL MEMBERS

### 5.1 Evaluation of Membership Applications for International Members

- 5.1.1 **Patient Caseload:** International Member applicants must care for a minimum of 150 new invasive gynecologic malignancy cases per year. Of these 150 cases, 100 must be primary untreated cases. The remaining 50 may be previously treated cases.
- 5.1.2 **Multi-Disciplinary Requirements:** The GOG is a multi-disciplinary group, and multi-disciplinary representation should be included in each application. Each application for International Membership must have a Gynecologic Oncologist, preferably Board Certified, and a Pathologist as participating members of the team. Medical Oncology and/or Radiation Oncology must also be represented on the institutional team. Preferably, both disciplines should be represented. Letters of intent from a representative of each discipline must accompany the application, and must identify the GOG Principal Investigator for the Institution.
- 5.1.3 **Institutional support:** The CEO or Director of Research at the proposed institution must submit a letter in support of the application, stating whether the application is for International membership. This letter must include a statement regarding financial support. This letter must indicate an Institution commitment to continue the submission of follow-up data on patients entered on protocol, even in the event the proposed Principal Investigator (“PI”) leaves the institution.
- 5.1.4 **Previous GOG Experience:** The GOG Administrative Office and Statistical Data Center will supply the Membership Committee with data outlining the proposed International Member institution's previous GOG participation, if any. This will include accrual data, a review of completeness, eligibility, evaluability, and reports of previous audits and data assistance reviews.
- 5.1.5 **Deadline for International Membership Application:** The completed Membership Application must be returned to the GOG Administrative Office **45 days** prior to a Semi-Annual Meeting to be considered at that meeting. A completed application contains an Invasive Gynecologic Malignancy Form signed by the PI, a completed

questionnaire, a letter of support from the Institution's Department Chair, and letters of support from a representative of each discipline that will participate in GOG protocols and activities.

5.1.6 The PI from the applicant institution should attend the Semi-Annual Meeting at which the application will be reviewed. The Membership Committee may request that the PI attend the Membership Committee Meeting during which the application is considered.

5.1.7 **Granting International Membership:** International Membership may be granted at a Semi-Annual Meeting, on the recommendation of the Membership Committee and with the approval of the Board of Directors.

## 5.2 **Evaluation of Membership Applications for International institutions affiliating with non-International GOG Members**

International institution wishing to affiliate with non-International GOG members must submit a GOG Affiliate Membership application. These applications will be evaluated in accordance with the standard Affiliate Membership application review process. (See Section 4.0)

## 5.3 **Membership Standards for Continuing International Membership**

An International Member institution is expected to be able to meet membership requirements on its own and should not have to rely on cases entered from its affiliates to maintain International Membership, **except in the cases when the International Member is itself a Clinical Trials Cooperative Group.**

5.3.1 **Timing of Review:** Evaluation of International Members will take place at least semi annually.

5.3.2 **Protocol Participation:** International Members must have at least one Phase III protocol open and have a minimum of 36 points from Phase III Studies accrued per annum.

5.3.3 **Eligibility and Evaluability:** Ninety percent (90%) of all cases entered must be eligible and ninety percent (90%) of all eligible cases must be evaluable.

5.3.4 **Completeness of Data:** Eighty-five percent (85%) of all records must be complete at all times and eighty-five percent (85 %) of follow-up forms must be complete.

5.3.5 **Meeting Attendance:** At least one representative of the International Member must attend one meeting each year.

- 5.3.6 **Audits:** International Members will be audited within 12-18 months after placing their first patient on a protocol.

## 6.0 Gynecologic Cancer Intergroup (GCIG) Membership

### 6.1 Evaluation of GCIG Membership Applications

- 6.1.1 **Multi-disciplinary Representation:** Each GCIG Group Member must have a full-time Pathologist. A Gynecologic Oncologist, Medical Oncologist and/or Radiation Oncologist should be represented on the institutional team. Participation by all four disciplines is preferable.
- 6.1.2 **Previous GOG Experience:** Previous GOG participation, if any, will be reviewed including accrual data, a review of completeness, eligibility, and reports of previous audits and data assistance reviews.
- 6.1.3 **Granting GCIG Membership:** In order for the GCIG Group Member to participate in the GOG, an application must be submitted to the GOG Administrative Office in Philadelphia. The Membership Committee and the Board of Directors will be informed about new GCIG Group Members at the Semi-Annual Meetings. There is no deadline for GCIG Member applications.
- 6.1.4 **Changes to Provisional Membership Status:** A GCIG Group Member may become a Provisional or Full Member of the GOG if and when the GCIG Group Member fulfills all the requirements for that status.

### 6.2 Membership Standards for continuing GCIG membership with GOG

If the GCIG Group Member is not a Provisional or Full Member, it will be evaluated as follows:

- 6.2.1 **Timing of Review:** Evaluation of a Group Member will take place at the semi-annual meeting.
- 6.2.2 **Protocol Participation:** The GCIG Group Member must have at least one Phase III Protocol open, and a minimum of 6 patients entered on Phase III studies annually, if an appropriate trial is available.
- 6.2.3 **Eligibility and Evaluability:** Ninety percent (90%) of all cases entered on protocol must be eligible and ninety percent (90%) of all eligible cases must be evaluable.

- 6.2.4 **Completeness of Data:** Eighty-five (85%) of all records must be complete at all times. Eighty-five percent (85%) of follow-up forms must be complete.
- 6.2.5 **Meetings:** At least one representative of the GCIG Group Member must attend one meeting each year.
- 6.2.6 **Audits:** The GCIG Group Member will be audited within 12-18 months after placing their first patient on a protocol.

## 7.0 **CCOP/MBCCOP Membership**

There will be two types of CCOP/MBCCOP Members: Main CCOP/MBCCOP Members and CCOP/MBCCOP Components. Main CCOP/MBCCOP members most often serve as the Administrative Office for the CCOP/MBCCOP. The CCOP/MBCCOP Component sites are generally the locations where the CCOP/MBCCOP patients are consented and treated. Component sites are reviewed as part of one CCOP/MBCCOP Main Member.

The GOG recognizes the unique value that CCOPs provide to clinical research. Main CCOP/MBCCOPs will be Non-Voting GOG members. However, as a group, the CCOPs shall have one vote at the GOG Annual Membership Meeting and at any other Membership or PI meeting. CCOP representatives may serve on all committees, except the Board of Directors. The accrual requirement for CCOP institutions is six patients annually, with three of the six enrolled onto treatment trials. All other membership requirements, including eligibility, evaluability, completeness of records, follow-up records, audit reports and meeting attendance, will be enforced.

### 7.1 **Evaluation of CCOP/MBCCOP Membership Applications**

- 7.1.1 **Multi-disciplinary Representation:** Each CCOP/MBCCOP must have a full-time Pathologist. A Gynecologic Oncologist, Medical Oncologist and/or Radiation Oncologist should be represented on the institutional team. Participation by all four disciplines is preferable.
- 7.1.2 **Previous GOG Experience:** Previous GOG participation, if any, will be reviewed will include accrual data, a review of completeness, eligibility, evaluability, and reports of previous audits and data assistance reviews.
- 7.1.3 **Deadline for CCOP Membership Applications:** There is no deadline for CCOP Membership Applications. These applications are received, and reviewed year-round.
- 7.1.4 **Granting CCOP Membership:** In order for a DCP-approved CCOP to utilize the GOG as a Research Base, a GOG CCOP application must

be submitted to the GOG Administrative Office in Philadelphia. The Membership Committee and the Board of Directors will be informed about new CCOP members at the Semi-Annual Meetings.

- 7.1.5 **Changes to Provisional Membership Status:** A few CCOP participants may meet the accrual requirements to become Provisional Members (see 2.0). If they desire to be considered for this change, they should notify the Group Chair of their intent. The Membership Committee will then evaluate their status and make recommendations to the Group Chair.

## 7.2 **Membership Standards for Continuing CCOP Membership**

- 7.2.1 **Timing of Review:** Evaluation of CCOPs will take place at each regularly scheduled Semi-Annual meeting.
- 7.2.2 **Protocol Participation:** To continue membership in the GOG, CCOPs must enter a minimum of 6 patients onto GOG protocols.
- 7.2.3 **Eligibility and Evaluability:** Ninety percent (90%) of all cases entered must be eligible and ninety percent (90%) of all eligible cases must be evaluable.
- 7.2.4 **Completeness of Data:** Eighty-five percent (85%) of all records must be complete at all times, and eighty-five percent (85%) of all follow-up records must be complete.
- 7.2.5 **Meeting Attendance:** Attendance by a representative of the CCOP at each Semi-Annual Meeting is strongly encouraged.
- 7.2.6 **Multi-disciplinary Representation:** The proposed CCOP applicant institution must have participation at least two of the following disciplines: Gynecologic Oncology, Medical Oncology, Radiation Oncology and Pathology. One discipline must be Pathology.
- 7.2.7 **Audits:** The Audit Committee will supply the Membership Committee with a report of any recent audit of any CCOP. These reports will be used in the evaluation of the CCOP Member.

## 8.0 **CTSU INSTITUTIONS**

Institutions that enroll through the CTSU are not GOG member institutions, and their access to GOG protocols is limited to those studies that are listed on the CTSU menu. Evaluation of CTSU Institutions participating on GOG studies will take place at each regularly scheduled Semi-Annual Meeting. There is no accrual minimum set for CTSU institutions. There is no meeting attendance requirement for CTSU institutions. However, CTSU institutions

are welcome to attend the GOG Semi-Annual Meeting. The GOG does not set multi- disciplinary requirements for CTSU Institutions

## 9.0 **PROBATION**

Members of the GOG who have failed to maintain a satisfactory record of participation or to contribute adequately to the Group may be placed on probation on the recommendation of the Membership Committee and with the approval of the Board of Directors. For these Probationary Members, voting privileges will be withheld, but representatives will continue to hold existing committee memberships and offices. Representatives of Probationary Members may not be elected to an office nor appointed or reappointed to committees. Failure to correct deficiencies and meet all standards for Full Membership within a two year period, or worsening of deficiencies, shall be considered as a basis for termination. Per Capita funding to Probationary Members will be reduced to 80% of that given to Full Members.

### 9.1 **Membership Standards for Probationary Members**

- 9.1.1 **Timing of Review:** Evaluation of Probationary Members will take place semi-annually.
- 9.1.2 **Protocol Participation:** Institutions must participate in protocols such that a minimum of 100 High Priority Points and 150 Total Points are accrued per year. These requirements must be met prior to reinstatement to Full Membership.
- 9.1.3 **Eligibility and Evaluability:** Ninety percent (90%) of all cases entered on a GOG clinical trial must be eligible and ninety percent (90%) of all eligible cases must be evaluable. These requirements must also be met prior to reinstatement to Full Membership.
- 9.1.4 **Completeness of Data:** Eighty-five percent (85%) of all records must be complete at all times and eighty-five (85%) percent of follow-up forms must be complete. This requirement must also be met prior to reinstatement to Full Membership.
- 9.1.5 **Meeting Attendance:** A minimum of one member of the institutional team must attend each Semi-Annual Meeting.
- 9.1.6 **Multi-disciplinary Requirements:** Each Probationary Member should have a full-time Gynecology Oncologist and a Pathologist. A Medical Oncologist and/or Radiation Oncologist should be represented on the institutional team. Participation by all four disciplines is preferable.
- 9.1.7 **Audits:** The Audit Committee will supply the Membership Committee with a report of any recent audit of any Probationary Members and of its Affiliates. These reports will be used in the evaluation of the Probationary Member. An unacceptable audit of either the

Probationary institution or any of its affiliates, will likely lead to termination.

## 10.0 **TERMINATION**

10.1 Termination of an institution from the GOG may be recommended for any of the following reasons:

10.11 A Provisional Member that does not meet the standards for Full Membership within two years;

10.12 Probationary status that continues beyond **two** continuous years or upon the third occurrence within any given five-year period;

10.13 Upon the request of the Group Chair or the Board of Directors;

10.14 Requirements for representation at the Semi-Annual Meeting are not met;

10.15 Evidence of fraud or research misconduct in any GOG institution or in any of its affiliates:

10.16 Results of an audit discover significant deficiencies or failure to monitor affiliates;

10.17 Other reasons as deemed appropriate by the Membership Committee and approved by the Board of Directors;

10.18 Failure of an affiliate member institution to enroll three (3) treatment patients annually; or

10.19 Resignation.

## 10.2 Data Submission Requirements for Terminated Institutions

10.21 Terminated institutions are required to continue data submission for all patients in active treatment;

10.22 Terminated institutions are required to continue data submission for all patients in active follow-up;

10.23 Terminated institutions are required to obtain IRB approval for all studies where patient data is being submitted;

10.24 Institutions that submit patient data must maintain a valid Federalwide Assurance Number;

## 11.0 APPEAL PROCESS

- 11.1 Appeals of the decisions of the Membership Committee that result in a change of membership status for a Full Member institution may be made by the PI of that institution. **The appeal must be made at the Semi-Annual Meeting at which the Full Member institution was placed on Probation or Terminated.** Letter of Warning or advisory letters may not be appealed.
- 11.2 Appeal of termination of an Affiliate Member is to be made to the GOG Group Chair within 30 days of notification of the termination to the PI of the Parent member by the Administrative Office. These appeals are handled by the Group Chair and the Membership Appeals Committee.
- 11.3 All Membership Committee recommendations will be submitted to the Board of Directors, which will make the final membership decision.