Gynecologic Oncology Group

Membership Application
**Specialty Questionnaire**  
(To be completed by Provisional or Affiliate applicant)

<table>
<thead>
<tr>
<th>Administration</th>
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<tbody>
<tr>
<td>Gynecologic Oncology</td>
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<tr>
<td>Medical Oncology</td>
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<tr>
<td>Radiation Oncology</td>
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<tr>
<td>Pathology</td>
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**Invasive Gynecologic Malignancies**  
(To be completed by Provisional or Affiliate applicant)

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<thead>
<tr>
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<tbody>
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<td>Radiation Oncology</td>
<td>24</td>
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<td>Pathology</td>
<td>24</td>
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</table>

**Application for Affiliate Membership**  
(To be completed by Parent Institution only)

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Gynecologic Oncology</td>
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<td>Radiation Oncology</td>
<td>30</td>
</tr>
<tr>
<td>Pathology</td>
<td>30</td>
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</tbody>
</table>

**Letter of Agreement**  
(To be completed by Parent and Affiliate applicants)

**Checklist for Completed Applications**

**FWA for the Protection of Human Subjects**
GOG MEMBERSHIP APPLICATION

Specialty Questionnaire

Institution: __________________________________________

ADMINISTRATION

1. a. Will you assign a specific individual to be responsible for submission of required data?
   YES_______  NO_______
   
b. Will this individual be able to travel to a GOG orientation and training session?
   YES_______  NO_______

2. Will you provide this individual with the necessary administrative support to see that data required from all departments is submitted on time? YES_______  NO_______

3. Will you have the support to do the necessary paperwork involved in obtaining approval of GOG protocols by your institution’s Human Subjects Committee?
   YES_______  NO_______

4. Will you continue to submit patient follow-up data in the event your institution should withdraw or be terminated from the GOG or the proposed Principal Investigator should leave your institution?
   YES_______  NO_______

5. Does your institution have a Tumor Registry approved by The American College of Surgeons?
   YES_______  NO_______

________________________________________________________________________

Name and Title of individual completing the questionnaire

(Rev. 08/95)
GOG MEMBERSHIP APPLICATION

Specialty Questionnaire

Gynecologic Oncology

Institution: ________________________________

1. List names, addresses and telephone numbers of the Gynecologic Oncologists who will participate in the GOG and describe their role in relation to this research project.

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2. List the name, address and telephone number of the Department Head of Obstetrics and Gynecology.

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Name and title of individual completing this questionnaire (Rev. 08/95)
3. What are your sources of patients that you will enter onto GOG protocols, i.e., service, private service, affiliates, etc.?

4. Is your Department Chair willing to support you with data personnel, travel to meetings, postage, telephone costs, etc. until funds can be obtained from NCI via a grant application?

5. Name of Department Head.

6. Will your Department Head submit a letter with this application stating support for your GOG participation?

7. Will your institution continue to submit patient follow-up data in the event your institution is withdrawn or is terminated from the GOG or the proposed Principal Investigator leaves?

8. What percentage of patients with gynecologic malignancy is under gynecologic oncology control? Do you have a large number of patients with gynecologic malignancy over whom you have no control?

9. How many patients are referred directly to radiation oncology without your input or evaluation?

10. Have you discussed GOG with Medical Oncology, Pathology and Radiation Oncology? YES_______ NO_______ What are their comments? Do you have their full cooperation and support? If not, please explain below.
11. Who will administer the chemotherapy to the patients enrolled by you on to GOG protocols?

12. How many hospital beds are reserved for gynecologic oncology?

13. How much operating time is reserved for gynecologic oncology?

14. Will GOG patients be presented to a combined conference with medical oncology, pathology, radiation oncology, and other representatives?

15. Will you be able to attend both semi-annual GOG meetings? If you do not have NCI funding, who will support this travel?

16. Who will be responsible for having GOG protocols submitted and approved by your Institutional Review Board?
17. How do you plan to submit data in the time period required?

18. Will you have a data manager?

19. How will you register patients and complete the fast fact sheets?

20. Do you have institutional and departmental support for your participation in the GOG?

____________________________________________________________________

(Name and title of individual completing this questionnaire)

Date: _______________________

PLEASE ATTACH THE FOLLOWING:

a. A copy of the Curriculum Vitae for each individual listed in # 1 above

b. A letter of intent to participate in the GOG from each individual listed in #1 above

c. A letter from the Department Head indicating departmental approval for participation
GOG MEMBERSHIP APPLICATION

Specialty Questionnaire

Medical Oncology

Institution: _______________________________________________________

1. List names, addresses and telephone numbers of the Medical Oncologists who will participate in the GOG and describe their role in relation to this research project.

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(Rev. 08/95)
2. Is your department involved in competing studies or cooperative groups?
   a. If yes, which studies will have priority?
   b. Who will be responsible for making this decision?

3. Do you have in-house studies or projects that would compete for patients with GOG protocols? Which will have priority?

4. Are you involved in joint conferences with pathology, gynecologic oncology, radiation oncology and others? Describe conferences, who selects the topics, who participates, who attends and any other relevant information.

5. Describe, in detail, the relationship between medical oncology and gynecologic oncology.

6. Will the medical oncologist(s) participate actively in GOG protocols and activities? If no, please explain.

7. Who will administer chemotherapy to patients entered on GOG protocols?
8. Will you or a representative be available to attend GOG semi-annual meetings?

9. Do you have institutional and departmental support of your participation in the GOG?

10. List any additional participating medical oncologists and describe their role in relation to this research project.

(Name and title of individual completing this questionnaire)

(Date)________________________________

PLEASE ATTACH THE FOLLOWING

a. A copy of the Curriculum Vitae for each individual listed in #1 above

b. A letter of intent to participate from each individual listed in #1 above

c. A letter from the Department Head indicating departmental approval of GOG participation

(Rev. 08/95)
GOG MEMBERSHIP APPLICATION

Specialty Questionnaire

Radiation Oncology

Institution: ____________________________________________________________

1. List names, addresses and telephone numbers of the Radiation Oncologists who will participate in the GOG and describe their role in relation to this research project.

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(Rev. 08/95)
2. What portion of your gynecologic patients come from sources other than the gynecologic oncologists listed in the application?

3. Are you willing to enter these patients onto GOG studies and would this pose a problem with the referring physician?

4. Are you aware of, and do you approve of the required visit by the Radiological Physics Center personnel to measure output from your machines and check on your dosimetry techniques?

5. Are these groups of gynecologic patients or diseases that you would have standard treatment approaches for and that you would be willing to consider for randomized prospective clinical trials?

6. Do you handle all, a portion of, or only a very small number of the gynecologic patients being treated in your department?

7. Review of radiation port films is necessary for some protocols. How will you submit the films and other relevant data within the prescribed time limits? This may involve expenses to your department to duplicate and submit films.

8. Are you involved in joint conferences with gynecologic oncology, medical oncology and pathology?

9. Are you involved in other competing studies or cooperative groups?
10. Do you have in-house studies or projects that would compete with GOG protocols?

11. Do you have institutional and departmental support for your participation in the GOG?

________________________________________
(Name and title of individual completing this questionnaire)

Date: ______________________________

PLEASE ATTACH THE FOLLOWING

d. A copy of the Curriculum Vitae for each individual listed in # 1 above

e. A letter of intent to participate from each individual listed in #1 above

f. A letter from the Department Head indicating departmental approval of GOG participation

(Rev. 08/95)
GOG MEMBERSHIP APPLICATION

Specialty Questionnaire

Pathology

Institution: _________________________________________________________________

1. List names, addresses and telephone numbers of the Pathologists who will participate in the GOG and describe their role in relation to this research project.

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(Rev. 08/95)
2. How many gynecologic pathology cases do you see each year in your department?

3. What percentage of this number is seen initially at your hospital?

4. What percentage is a review of material referred to your department?

5. What is the nature of your referral system?

6. What is the degree of cooperation between the referring institution and your department?

7. Do you anticipate difficulty in obtaining additional materials for review or submission that might be required by any given GOG protocol?

8. Are you, as the designated Pathologist to work with the GOG, willing to spend the time and effort to comply with the needs of the GOG? This may include review of slides to be sent to Headquarters, completion of GOG Pathology forms, participation in slide reviews at semi-annual or interim meetings and service on committees.
9. Do you have institutional and departmental support for your participation in the GOG?

(Name and title of individual completing this questionnaire)

Date:____________________________

PLEASE ATTACH THE FOLLOWING

g. A copy of the Curriculum Vitae for each individual listed in #1 above

h. A letter of intent to participate from each individual listed in #1 above

i. A letter from the Department Head indicating departmental approval of GOG participation

(Rev. 08/95)
GOG MEMBERSHIP APPLICATION
INVASIVE GYNECOLOGIC MALIGNANCIES

INSTITUTION:_____________________________________________________________________

### PRIMARY INVASIVE CASES

<table>
<thead>
<tr>
<th>PRIMARY SITE</th>
<th># PTS. SEEN PREV. CALENDAR YEAR</th>
<th>ANTICIPATED # PTS. NEXT YEAR</th>
<th>TOTAL (ANALYTIC/NONANALYTIC)</th>
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<td>SUB-TOTAL</td>
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### RECURRENT

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<th>ANTICIPATED # PTS. NEXT YEAR</th>
<th>TOTAL (ANALYTIC/NONANALYTIC)</th>
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<td>ANALYTIC</td>
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<td>PRIMARY SITE</td>
<td># PTS. SEEN PREV. CALENDAR YEAR</td>
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<td>SUB-TOTAL</td>
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<tr>
<td>TOTAL PRIMARY AND RECURRENT CASES</td>
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The preceding Invasive Gynecologic Malignancy Caseload Data is accurate to the best of my knowledge.

**TUMOR REGISTRAR**

**DATE**

**OR**

**MEDICAL RECORDS LIBRARIAN**

**DATE**

*For definitions of primary, recurrent, analytical and non-analytical cases use the Guidelines for Tumor Registries published by the American College of Surgeons.*

“To be completed by each Affiliate or Full Member applicant.”
TO BE COMPLETED BY PARENT INSTITUTION

GYNECOLOGIC ONCOLOGY GROUP

APPLICATION FOR AFFILIATE MEMBERSHIP

PARENT INSTITUTION: ____________________________

AFFILIATE INSTITUTION: ____________________________

ADMINISTRATION:

1. a. Will you assign a specific individual to be responsible for submission of required data from the affiliate?
   Yes_____ No_____ 

   b. Who will enter patients?  Affiliate institution __________
                                   Parent institution __________

   c. Who will submit follow-up data?  Affiliate institution __________
                                   Parent institution __________

2. Will you provide your affiliate with the necessary administrative support and see that data required from all departments is submitted on time?
   Yes_____ No_____ 

3. Are you aware that the GOG does not fund affiliate institutions and that any funding will come from the parent institution?
   Yes_____ No_____
4. Please detail your plans for the financial support, if any, of your affiliate (i.e. parent funds, grant support, etc).

5. Will you submit the required documentation that your affiliate has GOG Protocols approved by the IRB? See Membership Standards Section 2.22
   Yes_____ No_____

6. Are you aware that you are required to periodically conduct audits of your affiliate and that the GOG cannot supply funds for this?
   Yes_____ No_____

7. Does your affiliate have a Tumor Registry approved by The American College of Surgeons?
   Yes_____ No_____

8. Who will have overall responsibility for GOG activities in your affiliate?

------------------------

GYNECOLOGIC ONCOLOGY:

1. What percentage and number of patients that you will enter will come from the affiliate?

2. Is your department willing to support your affiliate with postage, telephone calls, travel, etc.? (Affiliates are not directly funded, only the parent institution. Also forms, protocols, announcements, etc. will not be sent directly to affiliates. It is the responsibility of the parent to supply the affiliate.)
3. Will your department chairman submit a letter with the application stating support for your affiliate?

4. Will your affiliate have the support of its
   
   Medical Oncologist?

   Radiation Oncologist?

   Pathologist?

5. Who will enter the patients, you or your affiliate? (NOTE: The GOG recommends that the Parent institution enters the patients.)

6. Who will submit the required follow-up data and assure that it is accurate and timely Parent/Affiliate?

7. How do you plan to monitor your affiliate for delinquency, eligibility, evaluability, etc.?

8. Will your pathologist review pathology material for the affiliate prior to submission to GOG Headquarters?
9. How do you plan to monitor the requirements for protocol participation? (Sect. 2.22, 3.23)

10. Please detail your plans for monitoring GOG/NCI supplied investigational drugs at your affiliate.

11. What are your plans for conducting the required audits of your affiliate institution? Are you aware that the GOG cannot provide funding for this?

12. Does your proposed affiliate have the support of its Department Chairman of Obstetrics and Gynecology?

13. Does your Department Chairman support your application for an affiliate?

13. Who will serve as the investigator for the affiliate institution? (Name, Title, Address)
MEDICAL ONCOLOGY:

1. Is your proposed affiliate involved in competing studies, other cooperative
groups or CCOP's?

2. Which groups or studies will have priority and who in your affiliate will make this
decision?

3. Does your proposed affiliate have joint tumor conferences? Who is included
(Medical Oncology, Radiation Oncology, Pathology)?

4. Will the Medical Oncologist at your affiliate participate in GOG activities and
protocols?

5. Who, in your proposed affiliate, will administer chemotherapy to GOG patients?
6. Does your proposed affiliate have the support of the Medical Oncology Department Head for participation in the GOG?

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RADIATION ONCOLOGY:

1. Does your proposed affiliate have in-house or cooperative group radiation therapy studies that would compete with GOG studies?

2. Who will decide which has priority?

3. Is your proposed affiliate aware of the required visits by the Radiologic Physics Center to calibrate the output of the machines?

4. Does your proposed affiliate have joint tumor conferences involving the radiation therapist and the gynecologists?

5. Does your proposed affiliate have the support of its Chairman of Radiation Therapy for its participation in the GOG?
PATHOLOGY:

1. How many gynecologic pathology cases does your proposed affiliate see each year?

2. Will you have pathology material from your proposed affiliate reviewed by your pathologists?

3. Does your proposed affiliate have the support of the Pathology Department Chairman for the participation in GOG activities?

(Name and Title of Individual Completing This Questionnaire) (Date)

PLEASE ATTACH THE FOLLOWING:

1. The letter from your Department Head indicating support for your affiliate application.
2. A letter from the Department Head of your affiliate indicating support for participation.
3. Completed GOG Membership Application.
4. Curriculum Vitae for the proposed affiliate investigator and all other GOG participants.
5. Completed Affiliate Letter of Agreement.
LETTER OF AGREEMENT

between

GYNECOLOGIC ONCOLOGY GROUP

and

______________________________________________
(Affiliate Institution Name)

as an affiliate of

______________________________________________
(Member Institution Name)

duly agrees to act in accordance with the below listed POLICY STATEMENT FOR AFFILIATE MEMBERS OF THE GYNECOLOGIC ONCOLOGY GROUP. By the signature below of the Affiliate Senior Investigator, the Principal Investigator of the Member Institution and receipt of this signed agreement by the Administrative Office in Philadelphia, Pennsylvania, the Affiliate is officially registered as a "Full" or "Provisional" Affiliate Member of the Gynecologic Oncology Group. A "Full" Affiliate is identified as a previously approved Affiliate which has participated satisfactorily in Group activities for at least one year. A "Provisional" Affiliate member is identified as a new institution or an institution which has participated in the Group activities for less than one year.

POLICY STATEMENT

The participation of institutions who collaborate with the Gynecologic Oncology Group, funded by the National Cancer Institute to conduct research clinical trials, is an important component of the Clinical Trials Program. The contributions of affiliates are recognized by both the NCI and the Gynecologic Oncology Group. The following policy will be implemented in order to strengthen the relationship of affiliates with the Gynecologic Oncology Group, to assure compliance with federal regulations regarding treatment research, and to provide accurate and timely information on matters of scientific importance.

1. An Affiliate or satellite member is an institution which enters patients on research clinical trials through associations with a Gynecologic Oncology Group member, but who is not a formal member of the Gynecologic Oncology Group. Each affiliate institution must have demonstrated competence in the treatment of cancer patients as defined by the Gynecologic Oncology Group.

2. In order to qualify as an affiliate, an institution must have established a close cooperative relationship with a Gynecologic Oncology Group Full Member institution. This relationship should include a willingness to initiate regular participation in cooperative group meetings and/or educational sessions sponsored by the Gynecologic
Oncology Group once the affiliate status is officially established.

3. Each affiliate must demonstrate an ability to enter patients onto clinical protocols of the Gynecologic Oncology Group as a provisional affiliate member over a one year period. Prior to acceptance as a full affiliate, an assessment of the performance during the provisional period must be completed. This review will take into account the results of an audit of the affiliate as well as an assessment by the Statistical Office of the quality of the data.

4. Affiliate members shall agree to adhere to all procedures of the Gynecologic Oncology Group and the National Cancer Institute for the conduct of clinical research. As a minimum this would involve:
   a. Meeting the record keeping policies of the Gynecologic Oncology Group.
   b. Documented assurance that each protocol has approval by the Institutional Review Board (IRB). The IRB must agree to review the research protocols of the affiliate. The IRB must have an assurance document which has been approved by the Office for Protection from Research Risks (OPRR).
   c. Documentation that each patient has signed and has a copy of the IRB approved consent form.
   d. Documented compliance with the policies of the NCI and regulations of the FDA concerning the use of investigational drugs.
   e. Agreement of the proposed affiliate that the primary medical records of the patients may be audited in accordance with policies of the Gynecologic Oncology Group, NCI, FDA, and other authorized Government agencies.

5. In accordance with NCI policy, all provisional and full affiliate members shall be registered with the Gynecologic Oncology Group Headquarters and NCI. Affiliate members will file a signed FD-1573 with NCI prior to participating in any research protocol utilizing investigational drugs. Investigational drugs will not be provided to unlisted investigators by the Gynecologic Oncology Group Headquarters or parent member institution, and will not be used to treat patients who have not been properly registered onto NCI approved Gynecologic Oncology Group protocols.

6. Affiliate members will be subject to the same site visit and performance evaluations as regular full group members.
GYNECOLOGIC ONCOLOGY GROUP

(SIGNATURE AND DATE)

(MEMBER INSTITUTION NAME)

(PRINCIPAL INVESTIGATOR SIGNATURE)

(DATE)

(AFFILIATE INSTITUTION NAME)

(AFFILIATE SENIOR INVESTIGATOR)

(DATE)
# CHECKLIST FOR COMPLETED APPLICATIONS

## PROVISIONAL

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<th>Represented disciplines</th>
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<td>(2 of 3 required and each * required)</td>
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<td>* Gynecologic Oncology (____)</td>
<td>Gynecologic Oncology (____)</td>
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<td>Medical Oncology (____)</td>
<td>Medical Oncology (____)</td>
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<tr>
<td>Radiation Oncology (____)</td>
<td>Radiation Oncology (____)</td>
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<tr>
<td>*Pathology (____)</td>
<td>*Pathology (____)</td>
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| Letter from Department Chair (____) | Letter from Department Chair (____) |
| Tumor Caseload Form (____) | Tumor Caseload Form (____) |

## AFFILIATE

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<th>Represented disciplines</th>
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<td>*Pathology (____)</td>
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<tr>
<th>Letters of Support</th>
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<tr>
<td>(Required for represented Discipline)</td>
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<tr>
<td>*Gynecologic Oncology (____)</td>
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<td>Medical Oncology (____)</td>
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<tr>
<td>Radiation Oncology (____)</td>
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<tr>
<td>*Pathology (____)</td>
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Completed applications are due 30 day prior to the next regularly scheduled Semi-annual business meeting, to be acted on during that meeting.

Completed application should be submitted to the GOG Administrative Office.
U.S. Department of Health and Human Services (DHHS)
Federalwide Assurance (FWA) for the Protection of Human Subjects
For U.S. and Non-U.S. Institutions

Forms and Instructions can be obtained from the following website:

http://ohrp.osophs.dhhs.gov