



Cancer and Leukemia Group B  
Central Office of the Chairman

230 West Monroe Street, Suite 2050  
Chicago, IL 60606-4703  
TEL (773) 702-9171  
FAX (312) 345-0117

[www.calgb.org](http://www.calgb.org)

Richard L. Schilsky, M.D.  
Chairman

**TO:** Investigators interested in applying for CALGB institutional membership

**FROM:** CALGB Regulatory Affairs Coordinator (Rena Williams, phone: 773-702-9860 or e-mail: [williamr@uchicago.edu](mailto:williamr@uchicago.edu))

**DATE:** Revised December 16, 2005

A CALGB institution may be an academic medical center, cancer center, hospital, physician group, veterans administration hospital or military treatment facility. If you have any questions about the suitability of your application for CALGB institutional membership, please call/write the CALGB Regulatory Affairs Coordinator (named above).

CALGB has three types of membership: main member, at-large member and affiliate. A main member institution may have affiliate members or may be a stand-alone institution. The main member network is expected to have at least 50 registrations annually to CALGB clinical trials by the end of its second year. An at-large member institution may have affiliate members or may be a stand-alone institution. The at-large member network is expected to have at least 30 registrations annually to CALGB clinical trials by the end of its second year. An affiliate member must have sponsorship of a main member or at-large member in order to join the CALGB and is expected to have at least 6 registrations annually to CALGB clinical trials by the end of its second year. A list of CALGB main member and at-large institutions and their Principal Investigators are located on the CALGB web site. (<http://www.calgb.org>)

A main member, at-large member or affiliate may be any type of institution, (i.e., an academic medical center, cancer center, hospital, physician group, a veterans administration hospital or a military treatment facility). All institutions must follow the same federal regulations:

The institution must have a Multiple Project Assurance (MPA), a Cooperative Project Assurance (CPA) or a Federal wide Assurance (FWA) from the Office of Human Research Protections (OHRP). If the institution does not have an assurance, it can submit an application for an assurance to the CALGB Central Office at the same time that the membership application is submitted. Sample assurance document forms may be obtained from the OHRP web site:

[http://www.hhs.gov/ohrp/assurances/assurances\\_index.html](http://www.hhs.gov/ohrp/assurances/assurances_index.html)

All investigators who are in private practice or belong to a physician group and will have their protocols reviewed by an institution must have a Non-Institutional Investigator Agreement (NIA), an Unaffiliated Investigator Agreement (UIA) or an Agreement for Independent Investigator (AII) on file. The NIA/UIA/AII should be located at the institution that has agreed to review the protocols. A copy of the NIA/AII may be obtained at the following website:

<http://www.hhs.gov/ohrp/humansubjects/assurance/asur.htm>. A copy of the UIA may be obtained at the following website:

[http://www.hhs.gov/ohrp/assurances/assurances\\_index.html](http://www.hhs.gov/ohrp/assurances/assurances_index.html).

The National Institutes of Health (NIH) requires that everyone involved in clinical trials complete educational training regarding the protection of human subjects. Everyone who assists in conducting a clinical trial, i.e., physicians, nurses, clinical research associates, pharmacists and support staff, etc are required to have this training. Although everyone is required to obtain the training, certification that the training has been completed is only required for investigators involved in the design or conduct of the trial, as well as for those investigators responsible for consenting patients to participate in any CALGB protocol. Investigators who have not completed the training will NOT be permitted to enroll patients on CALGB trials.

The CALGB Central Office will accept certification from a variety of sources including but not limited to any Institutional Review Board sponsored training program, NIH intramural training, "Protection of Human Research Subjects: Computer-Based Training for Researchers" - available at <http://ohsr.od.nih.gov/cbt/>, "Human Participant Protections Education for Research Teams": continuing medical education (CME) credits for physicians - available at <http://cme.nci.nih.gov>, and University of Rochester training program which involves reading a book, "Protecting Study Volunteers in Research" and completing and mailing in a test. The book may be ordered from: <http://www.centerwatch.com>.

The Cancer Therapy Evaluation Program (CTEP) requires that all investigators, **regardless of specialty**, have an NCI Investigator Number and their FDA 1572 form, with original signature, on file with NCI. Effective March 1, 2002, NCI Investigator numbers must be submitted on all investigators' roster update forms. If you are not aware of what your NCI Investigator Number is, you can request your NCI number by contacting Beverly Bailey at the Pharmaceutical Management Branch at 301-496-5725. If you do not have a NCI Investigator Number, you can obtain one by filling out the FDA 1572 form and submitting it to NCI. The FDA 1572 form can be obtained at the following web site: <http://ctep.cancer.gov/forms/index.html>.

The institution must have on file a statement that the institution has a plan in place for notifying patients of new information, if it becomes available, regarding the treatment they received. It is not necessary to provide CALGB the specifics of the plan.

Audits will be conducted at each institution and the institution is responsible for collecting all the medical records if the patient was treated at other locations.

Each institution will be responsible for ordering and tracking investigational drugs according to the policies outlined in the National Cancer Institute Investigator's Handbook. The Investigator's Handbook is on the web at the following address: <http://CTEP.info.nih.gov/handbook>.

Several other forms must be submitted along with the membership application. A Roster Update Request Form must be completed for each individual whom you wish to be considered for membership in the CALGB. A curriculum vitae must be included for each physician member. Each new CALGB participant must sign a Scientific Misconduct Form indicating that he/she has read the CALGB policy regarding scientific misconduct. If your institution plans to enroll patients on radiation therapy studies, a Radiation Facility Inventory Form must be completed and submitted. Your institution must sign a Services Agreement, that outlines responsibilities of membership in CALGB, and also permits CALGB to pass through to you per-case payments from federal funds for which your institution is eligible. Per-case payments, in general, are available to defray costs related to enrollments to CALGB treatment studies, selected ancillary studies, selected cancer control and prevention studies, etc. At this time, institutions holding Community Clinical Oncology Program grants at the time of the registration are not eligible for most per-case payment programs, and CALGB institutions holding main member federal grants are not eligible for selected per-case payment programs.

Before completing the application, please confirm with an institutional official that you are using the accurate legal name of your institution. The membership packet contains all forms that must be completed for your membership except for the OHRP assurance document, if applicable.

If you have any questions regarding the application materials, please call the CALGB Regulatory Affairs Coordinator, Rena' Williams at 773-702-9860 or e-mail: [williamr@uchicago.edu](mailto:williamr@uchicago.edu).

# CALGB INSTITUTIONAL MEMBERSHIP APPLICATION

Your complete application package must include the following documents:

- **Letter of Support from the Principal Investigator of the Main Member or At-Large Member(affiliate applicants only)**
- **Completed Membership Application**
- **Federal wide Assurance Application/Documentation**
- **Radiation Therapy Facilities Inventory**
- **Patient Notification Letter**
- **Laboratory Normal Values and Laboratory Certification**
- **Roster Update Forms and CVs/Non-Investigational Agreement/Unaffiliated Investigator Agreement/Agreement for Independent Investigator/Investigator's NCI Identification Number/Investigator's 1572 and Financial Disclosure Form**
- **Certification on Protection of Human Subject Training**
- **Scientific Misconduct Forms**
- **Service Agreement and Vendor Certification**

*(If application is incomplete, it will be tabled until the next semiannual Membership Committee meeting)*

**APPLICATION TYPE:** (Please check one)

**MAIN MEMBER:** \_\_\_\_\_  
(Annual Accrual Required - 50 Registrations)

**AT-LARGE MEMBER:** \_\_\_\_\_  
(Annual Accrual Required - 30 Registrations)

**AFFILIATE:** \_\_\_\_\_  
(Annual Accrual Required - 6 Registrations must be sponsored of Main Member or At-Large Institution)

Complete this application in *proposal* format where applicable to be reviewed by the CALGB Membership Committee. We prefer concise and convincing replies over length. Responses that address the questions by presenting tabular information are encouraged. Do not refer the reviewer to documentation not included in this application.

Legal Name of Institution: \_\_\_\_\_

(Confirm the legal name with an institutional official.)

Legal Address of Institution: \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip + 4 \_\_\_\_\_

*Applications will be delayed until this information is provided. It is a NIH requirement.*

Name of Academic Affiliation, if any: \_\_\_\_\_

Name of Principal or Responsible Investigator: \_\_\_\_\_

Name of Lead CRA: \_\_\_\_\_

**IRB Information:**

Specify IRB Location: \_\_\_\_\_

Do you have an OHRP Assurance?      Circle one: Yes   No

If "yes," provide your current Assurance number, its expiration date, and attach a copy of your assurance to this application.

If "no," attach the original of a completed, signed OHRP Assurance Application on the hospital's/institution's stationery. (*This form is on the OHRP web site at <http://ohrp.osophs.dhhs.gov/irbasur.htm>*)

**Radiation Oncology Information:**

Will patients entered at this facility have access to Radiation Therapy? Circle one: Yes No.

If "yes," list each RT facility that you plan to use and attach a completed Radiation Therapy Facilities Inventory for each site:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Funding:**

Does a Community Clinical Oncology Program Grant currently fund your institution/group? Circle one: Yes No

If "yes," indicate the grant number and funding period.

Grant # \_\_\_\_\_ Funding Period \_\_\_\_\_

If you are forming a CALGB network that is participating in the CALGB Minority Initiative Program (MIP), indicate if this institution should be included in the MIP Program. Circle one: Yes No

(The MIP designation is only applicable for new affiliates joining a currently funded MIP network. Check with your PI.)

**Patient Notification Policy:**

Include in your application a letter to Richard L. Schilsky, M.D., Group Chair, co-signed by an appropriate institutional official, that states that your institution has a plan in place for notifying patients of new information if it becomes available, regarding the treatment they received. It is not necessary to provide the specifics of the plan.

**Laboratory Normal Values and Certification:**

Submit a copy of your laboratory normal values and laboratory certification.

**Investigators/Support Personnel:**

Submit a Roster Update Form for each proposed participant, a copy of their certification on Protection of Human Subject Training and a signed copy of the Individual Scientific Misconduct form. In addition, please submit a Curriculum Vitae (CV) for each physician who plans to register patients and a Non-Investigational Agreement/Unaffiliated Investigator Agreement/Agreement for Independent Investigator Form if applicable. All Roster Update Forms for physicians must include their NCI Identification Number.

**Membership Proposal:**

1. Describe the support resources available to assure timely compliance with Group administrative and data requirements, e.g., oncology nurses, clinical research associates, administrative support for IRB requirements. If you are proposing affiliate sites, describe the organization of your data management services in some detail, especially how you will approach quality control of the data submitted to CALGB.
2. Describe your pharmacy resources and how you plan to handle investigational drugs that are part of CALGB research.
3. Document adequate patient resources available for entry into clinical trials. List your annual caseload by hospital and by disease and cite the source of the data (tumor registry, etc.).
4. Indicate anticipated accrual by types of studies (by disease or committee). You may wish to consult a recent Protocol Status list, which shows the current studies by committee, so you can make accurate accrual projections. This list is on the CALGB web page or available upon request from the Regulatory Affairs Coordinator (773-702-9860).

Specify any disease areas (or committees) of CALGB research in which you do NOT foresee participation.

5. Discuss any preclinical or other special resources which could benefit the Group's current scientific directions. *(For Main Member Applicants Only)*
6. Describe your *current non-cooperative group cancer* research programs. Describe your accruals to clinical trials for the past three years and cite evaluability rates of patients entered onto study. Any audit reports or monitoring reviews by outside reviewers could be attached as an appendix. *(For Main Member and At-Large Member Applicants Only)*
7. Describe any prior or current cancer research cooperative group experience of your institution. If this institution is currently a member of any other adult, multimodality cooperative group, explain future plans if accepted to CALGB.
8. Provide any other information that you feel is important to the review of this application.
9. Name **Modality Physician Coordinators** and attach a Letter of Support/Intent from each: *(For Main Member and At-Large Member Applicants Only)*

Medical Oncology:

Hematology:

Surgery:

Radiation Oncology:

Pathology:

Cytogenetics:

Psycho-Oncology:

Cancer Control:

10. **List the institutions or physician practices if applicable** to be included in your application. Complete a separate CALGB Institutional Application and Letter of Intent for each institution named below. (*For Main Member and At-Large Member Applicants Only*)

Name of Affiliate Institution:  
Responsible Investigator:

Name of Affiliate Institution:  
Responsible Investigator:

Name of Affiliate Institution:  
Responsible Investigator:

Name of Affiliate Institution:  
Responsible Investigator:

Name of Affiliate Institution:  
Responsible Investigator:

Name of Affiliate Institution:  
Responsible Investigator:

Name of Affiliate Institution:  
Responsible Investigator:

<b>Application submitted by</b>	<b>on:</b>
<i>Signature of Proposed PI/RI</i>	<i>date</i>

Return Completed Application to:  
Regulatory Affairs Coordinator  
CALGB Central Office of the Chairman  
230 West Monroe St., Suite 2050  
Chicago, IL 60606-4703

**CALGB Radiotherapy Facilities Inventory**

Radiotherapy Facility Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

Mailing Address: \_\_\_\_\_

(if different from above) \_\_\_\_\_

\_\_\_\_\_

Is this institution known by another name? \_\_\_\_\_

For the department of Radiation Oncology: Phone: \_\_\_\_\_

FAX: \_\_\_\_\_

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**Personnel**

**Chief Radiation Oncology**

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Phone: \_\_\_\_\_

FAX: \_\_\_\_\_

e-mail: \_\_\_\_\_

\_\_\_\_\_

**Chief Physicist**

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Phone: \_\_\_\_\_

FAX: \_\_\_\_\_

e-mail: \_\_\_\_\_

\_\_\_\_\_

**Clinical Physicist/Dosimetrist**

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Phone: \_\_\_\_\_

FAX: \_\_\_\_\_

e-mail: \_\_\_\_\_

\_\_\_\_\_

**Personnel**

**Principal Investigator - CALGB**

Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Phone: \_\_\_\_\_  
FAX: \_\_\_\_\_  
e-mail: \_\_\_\_\_  
\_\_\_\_\_

**Responsible Rad. Oncologist - CALGB**

Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Phone: \_\_\_\_\_  
FAX: \_\_\_\_\_  
e-mail: \_\_\_\_\_  
\_\_\_\_\_

**Data Manager / CRA - CALGB**

Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Phone: \_\_\_\_\_  
FAX: \_\_\_\_\_  
e-mail: \_\_\_\_\_  
\_\_\_\_\_

**Rad. Oncology Data Manager - CALGB**

Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Phone: \_\_\_\_\_  
FAX: \_\_\_\_\_  
e-mail: \_\_\_\_\_  
\_\_\_\_\_



Please fax or mail this form back to the CALGB Central Office:

Cancer and Leukemia Group B  
230 W. Monroe Street, Suite 2050  
Chicago, IL 60606-4703  
Fax: (312) 345-0117

I have read and I understand CALGB policies and procedures in section 3.4, Individual Scientific Misconduct.

Print Name \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

### **3.4 Individual scientific misconduct (Taken from the CALGB Policies and Procedures Manual)**

The Institutional Performance Evaluation Committee (IPEC) periodically reviews the performance of the individual member institutions of the CALGB. Annually it furnishes a report to CALGB main members concerning their performance. It also renders reports of its findings to the Membership Committee. The Membership Committee, in turn, makes reports to the Board of Directors. It bases its recommendations on the findings of the IPEC and any additional sources of information it may choose to employ. The Board of Directors may find that institutions are in good standing, place them on probation, or remove them from membership in the Group.

The integrity of CALGB data is dependent upon the work of many individuals at all levels of the Group. No event is more damaging to the reputation of the clinical research that CALGB and the other cooperative groups perform than the discovery of submission of false or fraudulent data. Inclusion of such data in our analyses may invalidate the scientific conclusions reached. These invalid conclusions may result in the setting of inappropriate medical practice standards consigning large groups of patients to inferior therapy. Moreover, the violation of the trust between the patient and the health-care team by such an event will erode the relationships required for conduct of clinical trials and poison the public's perception of all medical investigations. As such, evidence of any systematic or intentional attempt to submit false data of any sort to the CALGB will be dealt with in the most rapid and vigorous manner possible. In addition to withdrawing CALGB membership from those affected, and suspending accrual from the institution(s), the CALGB will assist appropriate governmental bodies in the prosecution of the individuals involved.

Through its audit program and other mechanisms the CALGB will search for any evidence submission of false data (see Sections 2.8 and 8.3). Two instances of scientific misconduct have been detected over the course of 600 audits conducted by the Group; both resulted in severe penalties. One investigator was convicted of a felony, fined \$20,000 and received a one year (suspended) jail sentence.

The CALGB publicizes its policies concerning scientific misconduct during the semiannual Group Meeting plenary sessions, data management workshops, the Group newsletter, and other means. Specific training sessions in ethics for investigators, Clinical Research Associates, statisticians, and other personnel are offered regularly.

This training includes instructions on means whereby CALGB members can bring possible instances of scientific misconduct to the attention of those required to investigate it, how to deal with improper data that may have been recorded, and how to correct, if necessary, the scientific record based upon data that are inaccurate.

#### **3.4.1 Receipt of allegations of scientific misconduct**

Individuals who have been asked to falsify data or who believe they have knowledge that others are falsifying data must inform the Regulatory Affairs Coordinator at the Central Office as soon as possible via whatever means (phone, letter, fax, e-mail, personal contact) is practical. The Regulatory Affairs Coordinator will complete a detailed accounting of the notification. If this notification occurs by phone, the Regulatory Affairs Coordinator will ask the party making the call if a witness to the call is desired. The policies of CALGB and NCI require a thorough investigation of any allegation of scientific misconduct while at the same time taking whatever actions are reasonable and proper to preserve the confidentiality of the informant

and, until misconduct is proven, to protect the reputation of those accused. Although anonymous calls for the purpose of notification are discouraged since they may lead to less effective resolution of the matter, they will, nevertheless, be accepted. This notification does not supersede or replace any notification also required by the institution from which the report originates. CALGB members should contact the grants and contracts offices of their institutions to ascertain the correct procedures for reporting such matters at their institution.

### **3.4.2 Processing of allegation within CALGB Central Office**

Upon receipt of an allegation of scientific misconduct, the Regulatory Affairs Coordinator must immediately bring the matter to the attention of the Group Chair or in the absence of the Group Chair, the Executive Officer, or in the absence of the Executive Officer, the Group Administrator. In instances when the notification is by phone, it is anticipated that one of above described persons will serve as a witness to the phone call.

When notification of the Central Office is complete, the Group Chair, Executive Officer, or Group Administrator along with the Regulatory Affairs Coordinator as a witness, will immediately phone CTEP Clinical Trials Monitoring Branch to report the incident. Subsequent to this notification, other actions may be required. These may include the immediate suspension of accrual to protocols in the involved institution and further investigation (see below).

### **3.4.3 Investigation of the allegation**

In concert with NCI, Office of Research Integrity or other pertinent individuals, bodies or agencies, CALGB will develop and implement a plan to investigate the allegation. With data that has already been submitted this investigation will usually consist of a thorough audit (see Section 2.8). However when the individual involved has been requested to submit false data, but has not actually done so, other actions, including entrapment, may be employed.

The terms to be used by various committees and officers in connection with the investigation of possible episodes of scientific misconduct have been deliberately chosen to remove any restriction or impediment to whatever action CALGB Committees, Executive Committee and Board of Directors may eventually choose to take in a given case. The CALGB may take action against a member or institution independently whether or not the individual is found guilty in civil or criminal proceedings by others.

The terms used in the audit section of these policies to define institutional performance are used to describe adherence to protocol as well as the quality of data and other submitted materials. In this section we distinguish between erroneous data that results from unintentional mistakes and omissions, and data which is systematically erroneous or untrue.

It is acknowledged that in any process as complex as clinical research occasional errors of many sorts may occur. These may include typographical mistakes, miscalculations of numeric data, omissions of tests, doses, or procedures, delays of treatments, etc. These events when encountered will be characterized by the terms used in the audit section and may generate actions concerning the institution as specified elsewhere in these policies.

Falsification of information is to be distinguished from inaccuracies arising from sources in the preceding paragraph. Examples would be an ineligible patient falsely made eligible, a non-responding patient said to have responded, an abnormal laboratory result made normal, omitted doses of treatment said to have been given, etc. When wrong information is provided systematically, an intent to deceive may be inferred. Occasional divergences of opinion among investigators are to be expected in any clinical trial, and data arising from such divergences are to be distinguished from those that are systematic attempts to deceive. When necessary, the CALGB Audit Committee, IPEC Committee, Membership Committee, Executive Committee, and Board of Directors will render judgment as to whether a given problem represents scientific misconduct and take appropriate actions as defined elsewhere in these policies.

Notwithstanding procedures for revoking membership, halting institutional accrual, or taking other action as defined in these policies or in the CALGB Constitution and Bylaws, the Chair of CALGB will take immediate action as defined here when allegations or proof of scientific misconduct occurs within CALGB.

#### **3.4.4 Actions to be taken if allegation of scientific misconduct is proved**

If false data has been submitted to the CALGB Data Management Center, it is segregated and dealt with according to the section on statistical handling of the data.

#### **3.4.5 Publication and retractions**

If the data have been used in any analyses in preparation of an abstract, the abstract will be revised, if possible, based on a new analysis without the suspect data, or a disclaimer will be offered during the presentation of the revised data. If such data have been used for preparation of a manuscript, the paper will be withdrawn until a new analysis can be conducted. If the manuscript with the false data has been published, the journal will be asked to publish a retraction and re-analysis at the earliest possible time.

It is understood that correction of published information derived from flawed data is of great importance to the public and the scientific community. The CALGB will issue such corrections to relevant journals within 30 days of the time that false data are discovered, or with CTEP consent, whenever a re-analysis can be completed. In addition CALGB has agreed to make its computer data and documentation available to CTEP for analysis when necessary in a national health emergency.

#### **3.4.6 Actions against individuals**

An allegation of scientific misconduct may result in immediate action on the part of the Group Chair to suspend patient registrations by a participant or a member institution. Subsequently, possible actions relevant to institutions will occur through usual committee processes described elsewhere in these policies.

Allegations of scientific misconduct by individuals will be brought by Central Office Staff, the Audit Committee, or others to the CALGB Executive Committee for investigation. Those accused may be asked to appear before the Committee. In such matters, because of the possibility of injury to patients or the public health, time is of the essence. The Executive Committee will set the schedule for the appearance and testimony of the accused. On the basis of the investigation, the Committee may either take no action

or may make recommendations to the CALGB Board of Directors. Recommendations to the Board may include severing the membership of the accused, removing the accused from study chairmanship or authorship, censure, or any other action the Executive Committee feels is appropriate.

The accused will be provided with the written recommendation of the Executive Committee to the Board. At the meeting of the Board, or in writing prior to the meeting, the accused may offer a rebuttal of the Executive Committee recommendations, but may not offer evidence not previously considered by the Executive Committee. The board will act on the recommendation of the Executive Committee, accepting it, rejecting it, or changing it as the Board deems appropriate.

### **3.4.7 Confidentiality**

The action of the Board is final and will be a matter of record. It will be documented in the minutes of the Board and communicated to the relevant CALGB institution. The deliberations of the Board, the Executive Committee, evidence and audits collected by the committees of the Group, and the statements of the accused will be held confidential by the CALGB. However, any and all evidence of misconduct will be shared with the NCI and/or other appropriate governmental bodies.



The University of Chicago

SERVICES AGREEMENT

CANCER and LEUKEMIA GROUP B (CALGB)
CASE STUDY SERVICES

Beginning Date:

Ending Date: See #1/Term

CALGB Grant No.

See Attachment A

CONTRACTOR/CALGB Member Institution:

Address:

CALGB Member Institution - Member I.D. #

National Cancer Institute (NCI) Code:

CALGB Principal/Responsible Investigator:

UNIVERSITY: The University of Chicago, Central Procurement Services, 1225 East 60th Street, Chicago Illinois 60637, Telephone: (773) 702-3320, FAX: (773) 702-0904.

The University of Chicago "UNIVERSITY" and CONTRACTOR/CALGB Member Institution (referenced above and hereinafter referred to as "CONTRACTOR" or "INSTITUTION") agree that CONTRACTOR will perform the professional services set forth upon the following terms and conditions:

1. TERM. This Agreement shall be in effect until such time that the CALGB Central Office is no longer a department of the University of Chicago, or unless terminated for other reasons per #5/Termination below.

2. SCOPE. The Cancer and Leukemia Group B (the "CALGB") is a national cooperative group of institutions ("main members or at-large members" and their "affiliate member" institutions) that conduct cancer treatment and prevention clinical trials and related research under the direction of a CALGB Principal Investigator (at "main member or at-large member" institutions) or Responsible Investigator (at "affiliate member" institutions) appointed at the institution. A main member or at-large member institution may have affiliate members or may be a stand-alone institution. An affiliate member must have sponsorship of a main member or at-large member in order to join the CALGB. The Professional Services Agreement herein embodies the agreement to participate as a member institution of the CALGB. This Agreement states the responsibilities of the CONTRACTOR named above in the conduct of all clinical trials under CALGB protocols.

Each CALGB main member or at-large member institution has its own unique relationship with its affiliate(s). However, the CALGB Central Office located at 230 W. Monroe St., Suite 2050, Chicago, IL 60606-4703, insures that all members follow federal regulations relating to research studies involving human subjects. The CALGB Central Office will communicate with its institutions, usually via the main member or at-large member institution, requesting any changes or, if it has questions regarding institutional compliance with federal regulations.

In addition, the CALGB has developed general policies that pertain to its member institutions.

3. INDEPENDENT CONTRACTOR. The CONTRACTOR agrees it is solely responsible for providing the labor to achieve the specified requirements. The CONTRACTOR agrees that the UNIVERSITY shall not provide training for the CONTRACTOR to perform services specified. The parties agree that the CONTRACTOR is an independent contractor and the UNIVERSITY has no right to control how the work is performed other than as specified for requirements as stated. The CONTRACTOR understands that no relationship other than that of contracting parties is established by this Agreement, and further understands that this does not establish any employer-employee arrangement. The CONTRACTOR agrees as an Independent Contractor to treat its assistants as its own employees and comply with tax requirements for CONTRACTOR and its assistants.

4. PROFESSIONAL SERVICES. In the conduct of the services the CONTRACTOR will observe the following provisions:

a. Conduct of Clinical Trials. The CONTRACTOR agrees to assume all responsibility to treat and follow patients according to CALGB protocols and CALGB policies and procedures and in compliance with federal regulations. Affiliate institutions may participate in protocols available via their main member or at-large member institution. The complete CALGB Policies and Procedures manual and CALGB Protocol List may be found on the World Wide Web at http://www.calgb.org. Updates to the CALGB Protocol List are provided on a monthly basis to affiliate institutions via the website or their main member or at-large member. In the event the Principal or Responsible Investigator leaves the institution, it is the institution's responsibility to make arrangements for continuity of treatment, follow-up, and data collection for patients already entered into CALGB studies.

**b. Human Subjects Protection.** CALGB Policies and Procedures, as they pertain to the approval and use of human subjects, shall be followed. HHS "Protection of Human Subjects" assurance/certification/declaration forms (Form 310) shall be submitted annually to the CALGB Central Office.

**c. Patient Accrual Requirements.** CALGB policies require that, beginning with the second year of membership, the main member network must be able to have 50 registrations annually to CALGB clinical trials. The at-large member network must be able to have 30 registrations annually to CALGB clinical trials, beginning with its second year. An affiliate member must be able to have 6 registrations per year to CALGB clinical trials, beginning with its second year. Each subsequent year, every institution will be evaluated and may lose its membership if it does not accrue the required number of credits annually. Each institution agrees to continue providing patient data for patients accrued to CALGB studies even if its membership is discontinued.

**d. Data Audit Requirements.** Each CALGB institution is audited at least every three (3) years but may be selected for audit each year. Each institution is responsible for any expenses incurred in audit preparations, i.e., charges for copying records, x-rays, etc. An institution, which requires more than one re-audit, due to an unacceptable performance rating, is required to pay for the expenses of the audit team. Medical records submitted in support of National Cancer Institute (NCI) multi-institutional clinical trials must conform to usual standards for the maintenance of clear, accurate and unambiguous medical records. White-outs on medical records are unacceptable.

If it is the usual and customary practice of a department, laboratory, clinic or office to prepare or issue official reports, then only that department, laboratory, clinic or office can change the report and that should be done by issuing a new, revised report. Any handwritten alterations of the medical record must be initialed and dated by the person making such alterations. For clinical progress notes, the change must be dated and initialed by the person making the change. Only one line should be placed through the initial entry, so that both the original entry and the change are legible.

**e. Patient Notification Policy.** The responsibility for notifying patients rests with the institution where the patient was enrolled on the clinical trial. Institutions that enter patients on clinical trials must state that they have a plan in place for notifying patients of new information. Member institutions must forward to the CALGB Central Office a letter, co-signed by an appropriate institutional official, that states that their institution has a plan in place for notifying patients of new information.

**f. Scientific Misconduct Policy.** Every CALGB member must have on file in the Central Office a copy of the acknowledgment form that they have read and understand CALGB policies and procedures in section 3.4, Individual Scientific Misconduct.

**g. Conflict of Interest.** Contractor shall disclose to the University any perceived or apparent conflict of interest related to the scope of work under this agreement. Further, all CALGB study chairs and co-chairs; committee chairs and vice chairs; members of the Central Office and Statistical Center staff; members of the Executive Committee and members of the Data and Safety Monitoring Board are required to submit a conflict of interest disclosure form annually to the CALGB Central Office. Contractor acknowledges that submission of Conflict of Interest disclosure forms is required when requested by the CALGB Central Office.

**h. Confidentiality.** Although there are some limits to non-disclosure of information to federal regulatory agencies, CALGB policy is to protect the privacy of subjects enrolled in CALGB trials to the extent allowed by the law. Contractor agrees that all clinical data, including but not limited to, case report forms, laboratory work sheets, slides, reports, materials, and all other information generated as a result of CALGB studies will be held, maintained, used and disclosed only in accordance with the study protocol, applicable CALGB policies and procedures in the use and disclosure of study data and protected health information, and the Health Insurance Portability and Accountability Act (HIPAA) and the privacy and security regulations promulgated thereunder. CALGB protocol consent forms further describe the steps to be taken by Contractor in this regard.

**i. Publications.** Any publication resulting from these studies shall be produced in accordance with CALGB policies. CONTRACTOR agrees that the support of the National Institutes of Health, Department of Health and Human Services will be acknowledged, whenever research projects funded in whole or in part by this support are publicized in any news media.

**5. TERMINATION.** This Agreement can be terminated before its expiration by either UNIVERSITY or CONTRACTOR given that written notice is provided to the other party at least thirty (30) days prior to the termination date. Termination includes termination for convenience.

**6. INDEMNIFICATION.** CONTRACTOR hereby undertakes and agrees to forever indemnify and hold harmless The University of Chicago and its Board of Trustees, individually and collectively, its subsidiaries and officers, agents, servants and employees of The University of Chicago, from any and all such losses, expenses, damages (including loss of use), demands and claims, and shall defend any suit or action brought against them, or any of them, based on any alleged injury (including death) or damage (including loss of use) arising out of performance of the work under this Agreement and shall pay all damages, judgments, costs, and expenses including attorney's fees in connection with said damages and claims resulting therefrom. The foregoing assumption, indemnification, hold harmless and undertaking of defense shall not apply to any loss, damage, expense, demand, claims or cause of action arising out of, or caused by the sole negligence of The

University and its Board of Trustees, individually or collectively, its subsidiaries or officers, agents, servants or employees of The University of Chicago.

**7. FEDERAL GOVERNMENT GRANT NUMBERS.** When a grant number is shown on the face of this purchase order, the purchase is being made under a grant from the U.S. Government, and certain provisions of that grant may apply to this purchase order. A copy of the grant provisions may be reviewed at the Office of Research Administration, 970 East 58th Street, 3rd Floor, Chicago, Illinois 60637.

**8. EXAMINATION OF RECORDS.** The CONTRACTOR agrees that the Buyer, the Federal sponsoring agency, the Comptroller General of the United States, or any of their duty authorized representatives, shall have access to and the rights to examine any directly pertinent books, documents, papers, and records of the CONTRACTOR, involving transactions related to this Purchase Order or Grant. The term "Purchase Order" or Grant" as used in this article excludes (1) Purchase Orders or Grants not exceeding twenty-five thousand dollars (\$25,000.00) and (2) subcontracts or Purchase Orders for public utility services at rates established for uniform applicability to the general public.

**9. EQUAL OPPORTUNITY.** During the performance of this Purchase Order or Contract, the CONTRACTOR agrees as follows:

a. The CONTRACTOR will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin. The CONTRACTOR will take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to their race, color, religion, sex, or national origin. Such action shall include, but not be limited to the following: employment, upgrading, demotion or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The CONTRACTOR agrees to post in conspicuous places, available to employees and applicants for employment, notices setting forth the provisions of this Equal Opportunity article.

b. The CONTRACTOR will, in all solicitations or advertisements for employees placed by or on behalf of the CONTRACTOR, state that all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, or national origin.

c. The CONTRACTOR will send to each labor union or representative of workers with which it has a collective bargaining agreement or other contract or understanding, a notice advising the labor union or workers' representative of the CONTRACTOR's commitments under the Equal Opportunity article, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

d. The CONTRACTOR will comply will all provisions of Executive Order No. 11246 of September 24, 1965 as amended by Executive Order No. 11375 of October 13, 1967, and of the rules, regulations and relevant orders of the Secretary of Labor.

e. The CONTRACTOR will furnish all information and reports required by Executive Order No. 11246 of September 24, 1965 as amended by Executive Order No. 11375 of October 13, 1967, and of the rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to its books, records, and accounts by the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.

f. In the event of the CONTRACTOR's noncompliance with the Equal Opportunity article of this Purchase Order or Contract, or with any of the said rules, regulations, or orders, this Purchase Order or Contract may be canceled, terminated, or suspended, in whole or in part.

g. The CONTRACTOR will include the provisions of paragraph 9a. through 9g. in every subcontract or Purchase Order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, so that such provisions will be binding upon each subcontractor or Purchase Order.

**10. FEE.** Member institutions may be funded either by: (1) their own CALGB U10 federal grant from the National Cancer Institute, (2) a combination of a U10 grant supplemented by per-case payments made to eligible institutions, or (3) per-case payment programs only. An overview of per-case payment programs currently available to eligible institutions is provided in Attachment A. CALGB Study Numbers eligible for this funding as well as updates are available at the CALGB website: <http://www.calgb.org> in the Members site, under Funding. CONTRACTOR, if eligible, shall be paid in accordance with these programs. CONTRACTOR's relationship shall be that of an independent contractor and UNIVERSITY shall not withhold taxes or Social Security payments from any sum paid to CONTRACTOR under this Agreement.

The CALGB Central Office will coordinate a per-accrual payment program using funds provided by the National Cancer Institute and other federal agencies, to defray the costs incurred in treating and following patients on selected CALGB clinical trials. The Central Office will prepare and pay invoices using information obtained from the CALGB Statistical and Data Management Center regarding patient registrations and randomizations attributable to your institution. Per-accrual payments will continue as long as funds for the designated program are available in each fiscal year. Institutions must remain members in good standing in CALGB to continue to be eligible for payments.

**11. NOTICES.** All notices and demands required thereunder shall be deemed given upon personal delivery or next business day following sending by reputable overnight delivery carrier or three (3) business days following sending by United States Registered or Certified mail, postage prepaid addressed to CONTRACTOR and UNIVERSITY, at the address first above written.

**12. CONTACT NOTICES.** For contract management purposes of this Agreement, the persons to be contacted to provide operations decisions on a daily basis on behalf of the parties shown below.

if to UNIVERSITY: Mary A. Sherrell, MA, Chief Financial Officer  
CALGB Central Office  
230 W. Monroe Street, Suite 2050  
Chicago, Illinois 60606-4703  
Telephone: 773-702-9856; Fax: 312-345-0117; msherrel@uchicago.edu

if to CONTRACTOR:

**13. NO WAIVER.** The failure of either party at any time to enforce any right or remedy available to it under this Agreement with respect to any breach or failure by the other party, shall not be construed to be a waiver of such right or remedy with respect to any other breach or failure by the other party.

**14. SEVERABILITY.** The presence in this Agreement of any clause, sentence, provision, paragraph or article held to be invalid, illegal or ineffective by a court of competent jurisdiction, shall not impair, invalidate or nullify the remainder of this Agreement. The effect of any such holding shall be confined to the portion so held invalid.

**15. HEADING.** The headings used in this Agreement are for convenience only and are not intended to be considered in construing its terms. The use in this Agreement of the terms "include"; "includes"; and "such as" shall be deemed in all cases to be followed by the words "without limitation."

**16. LAW.** This Agreement shall be governed by and construed in accordance with the laws of the State of Illinois.

**17. ENTIRE AGREEMENT.** This Agreement, the terms and conditions of the CALGB Policies and Procedures Manual, and amendments mutually agreed upon in writing are the complete and entire agreement regarding these transactions and replaces any prior oral or written communications between UNIVERSITY and CONTRACTOR.

**IN WITNESS WHEREOF,** the parties have executed this Agreement in two (s) counterparts, each of which shall be deemed an original and do hereby warrant and represent that their respective signatory whose signature appears below has been and is on the date of this Agreement, duly authorized to execute this Agreement.

**AGREED TO:  
CONTRACTOR:**

**THE UNIVERSITY OF CHICAGO  
CANCER AND LEUKEMIA GROUP B**

-----  
Signature  
-----  
Printed Name  
-----  
Title  
-----  
Date

-----  
Signature  
Richard L. Schilsky, M.D.  
Printed Name  
Chair, CALGB  
Title  
-----  
Date

**Read and Acknowledged By  
CALGB Principal/Responsible Investigator:**

-----  
Signature  
-----  
Printed Name  
-----  
Title  
-----  
Date



Cancer and Leukemia Group B  
Central Office of the Chairman  
230 W. Monroe Street, Suite 2050  
Chicago, IL 60606-4703  
TEL (773) 702-9171  
FAX (312) 345-0117

Richard L. Schilsky, M.D.  
Chairman

## Attachment A Study Funding List / September 2004

### **NCI Grant # CA37447 / CFDA # 93.399 / Division of Cancer Prevention and Control (DCP)**

Under this program, the CALGB Central Office provides per-case payments periodically to eligible institutions to support costs of participation in selected cancer control and prevention studies. Institutions which do not hold CALGB U10 CCOP grants are eligible to receive this funding. Payment amount is based on the credit value assigned by the DCP.

**NCI Grant # CA31946 / CFDA # 93.395 / Treatment Studies and Surgical Intrinsic Protocols (SIP)**  
Funding is available to provide per-patient reimbursements at \$2,000/patient. The purpose of this funding is to make cooperative group clinical research protocols available to community physicians so important research questions may produce results that are more generally applicable to community practice. The payments are intended to support data management effort and associated expenses of participating in CALGB treatment protocols. Institutions which do not hold CALGB U10 CCOP grants are eligible to receive this funding.

### **NCI Grant # CA31946 / CFDA # 93.395 / Minority Initiative Program (MIP)**

Funding is available to provide per-patient reimbursements at \$2,300/case (amount pending) for the Minority Initiative Program. The purpose of this program is to make cooperative group clinical research protocols available to community physicians so important research questions may produce results that are more generally applicable to community practice. The payments are intended to support data management effort and associated expenses related to participation by minority patients in CALGB treatment protocols. Institutions which do not hold CALGB U10 CCOP grants are eligible to receive this funding.

### **NCI Grant # CA31946 / CFDA # 93.395 / Ancillary Studies Program**

Funding is available to provide per-patient reimbursements at \$400/case for the Ancillary Studies Program. The purpose of the Ancillary Studies Program is to support data management costs of non-CCOP institutions associated with participation in CALGB non-treatment trials, as well as submissions of tissue blocks, bone marrow samples and plasma samples.

### **NCI Grant # CA31946 / CFDA # 93.395 / Patient Follow-up Program**

Funding available to provide per-patient reimbursements at \$50/case for support of Patient Follow-up expenses. Institutions which do not hold CALGB U10 CCOP grants are eligible to receive this funding.

### **NCI Grant # CA31946 (CFDA#93.395) and # CA85850 CFDA # 93.396) / Pathology Program**

Funding is available to provide per-patient reimbursements at \$50/case to the institutions of pathologists participating in CALGB Tissue Banking activities. These payments are intended to compensate institutional pathologists for the time devoted to procurement, processing and submission to CALGB Tissue Banks.

**NOTE: This list of CALGB Per-Case Payment Programs is provided as an overview only. CALGB Study Numbers eligible for this funding as well as updates are available at the CALGB website: <http://www.calgb.org> in the Member Site, under Funding.**

## Request for Taxpayer Identification Number and Certification

**Give form to the  
 requester. Do not  
 send to the IRS.**

<b>Print or type See Specific Instructions on page 2</b>	Name (as shown on your income tax return)	
	Business name, if different from above	
	Check appropriate box: <input type="checkbox"/> Individual/Sole proprietor <input type="checkbox"/> Corporation <input type="checkbox"/> Partnership <input type="checkbox"/> Other ▶ .....	
	Address (number, street, and apt. or suite no.)	Requester's name and address (optional)
	City, state, and ZIP code	
List account number(s) here (optional)		

### Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on Line 1 to avoid backup withholding. For individuals, this is your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the Part I instructions on page 3. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN* on page 3.

**Note.** *If the account is in more than one name, see the chart on page 4 for guidelines on whose number to enter.*

Social security number									
or									
Employer identification number									

### Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me), and
2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding, and
3. I am a U.S. person (including a U.S. resident alien).

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the Certification, but you must provide your correct TIN. (See the instructions on page 4.)

<b>Sign Here</b>	Signature of U.S. person ▶	Date ▶
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### Purpose of Form

A person who is required to file an information return with the IRS, must obtain your correct taxpayer identification number (TIN) to report, for example, income paid to you, real estate transactions, mortgage interest you paid, acquisition or abandonment of secured property, cancellation of debt, or contributions you made to an IRA.

**U.S. person.** Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN to the person requesting it (the requester) and, when applicable, to:

1. Certify that the TIN you are giving is correct (or you are waiting for a number to be issued),
2. Certify that you are not subject to backup withholding, or
3. Claim exemption from backup withholding if you are a U.S. exempt payee.

**Note.** *If a requester gives you a form other than Form W-9 to request your TIN, you must use the requester's form if it is substantially similar to this Form W-9.*

For federal tax purposes you are considered a person if you are:

- An individual who is a citizen or resident of the United States,
- A partnership, corporation, company, or association created or organized in the United States or under the laws of the United States, or

- Any estate (other than a foreign estate) or trust. See Regulations sections 301.7701-6(a) and 7(a) for additional information.

**Foreign person.** If you are a foreign person, do not use Form W-9. Instead, use the appropriate Form W-8 (see Publication 515, Withholding of Tax on Nonresident Aliens and Foreign Entities).

**Nonresident alien who becomes a resident alien.**

Generally, only a nonresident alien individual may use the terms of a tax treaty to reduce or eliminate U.S. tax on certain types of income. However, most tax treaties contain a provision known as a "saving clause." Exceptions specified in the saving clause may permit an exemption from tax to continue for certain types of income even after the recipient has otherwise become a U.S. resident alien for tax purposes.

If you are a U.S. resident alien who is relying on an exception contained in the saving clause of a tax treaty to claim an exemption from U.S. tax on certain types of income, you must attach a statement to Form W-9 that specifies the following five items:

1. The treaty country. Generally, this must be the same treaty under which you claimed exemption from tax as a nonresident alien.
2. The treaty article addressing the income.
3. The article number (or location) in the tax treaty that contains the saving clause and its exceptions.

4. The type and amount of income that qualifies for the exemption from tax.

5. Sufficient facts to justify the exemption from tax under the terms of the treaty article.

**Example.** Article 20 of the U.S.-China income tax treaty allows an exemption from tax for scholarship income received by a Chinese student temporarily present in the United States. Under U.S. law, this student will become a resident alien for tax purposes if his or her stay in the United States exceeds 5 calendar years. However, paragraph 2 of the first Protocol to the U.S.-China treaty (dated April 30, 1984) allows the provisions of Article 20 to continue to apply even after the Chinese student becomes a resident alien of the United States. A Chinese student who qualifies for this exception (under paragraph 2 of the first protocol) and is relying on this exception to claim an exemption from tax on his or her scholarship or fellowship income would attach to Form W-9 a statement that includes the information described above to support that exemption.

If you are a nonresident alien or a foreign entity not subject to backup withholding, give the requester the appropriate completed Form W-8.

**What is backup withholding?** Persons making certain payments to you must under certain conditions withhold and pay to the IRS 28% of such payments (after December 31, 2002). This is called "backup withholding." Payments that may be subject to backup withholding include interest, dividends, broker and barter exchange transactions, rents, royalties, nonemployee pay, and certain payments from fishing boat operators. Real estate transactions are not subject to backup withholding.

You will not be subject to backup withholding on payments you receive if you give the requester your correct TIN, make the proper certifications, and report all your taxable interest and dividends on your tax return.

**Payments you receive will be subject to backup withholding if:**

1. You do not furnish your TIN to the requester, or
2. You do not certify your TIN when required (see the Part II instructions on page 4 for details), or
3. The IRS tells the requester that you furnished an incorrect TIN, or
4. The IRS tells you that you are subject to backup withholding because you did not report all your interest and dividends on your tax return (for reportable interest and dividends only), or
5. You do not certify to the requester that you are not subject to backup withholding under 4 above (for reportable interest and dividend accounts opened after 1983 only).

Certain payees and payments are exempt from backup withholding. See the instructions below and the separate Instructions for the Requester of Form W-9.

## Penalties

**Failure to furnish TIN.** If you fail to furnish your correct TIN to a requester, you are subject to a penalty of \$50 for each such failure unless your failure is due to reasonable cause and not to willful neglect.

**Civil penalty for false information with respect to withholding.** If you make a false statement with no reasonable basis that results in no backup withholding, you are subject to a \$500 penalty.

**Criminal penalty for falsifying information.** Willfully falsifying certifications or affirmations may subject you to criminal penalties including fines and/or imprisonment.

**Misuse of TINs.** If the requester discloses or uses TINs in violation of federal law, the requester may be subject to civil and criminal penalties.

## Specific Instructions

### Name

If you are an individual, you must generally enter the name shown on your social security card. However, if you have changed your last name, for instance, due to marriage without informing the Social Security Administration of the name change, enter your first name, the last name shown on your social security card, and your new last name.

If the account is in joint names, list first, and then circle, the name of the person or entity whose number you entered in Part I of the form.

**Sole proprietor.** Enter your individual name as shown on your social security card on the "Name" line. You may enter your business, trade, or "doing business as (DBA)" name on the "Business name" line.

**Limited liability company (LLC).** If you are a single-member LLC (including a foreign LLC with a domestic owner) that is disregarded as an entity separate from its owner under Treasury regulations section 301.7701-3, enter the owner's name on the "Name" line. Enter the LLC's name on the "Business name" line. Check the appropriate box for your filing status (sole proprietor, corporation, etc.), then check the box for "Other" and enter "LLC" in the space provided.

**Other entities.** Enter your business name as shown on required Federal tax documents on the "Name" line. This name should match the name shown on the charter or other legal document creating the entity. You may enter any business, trade, or DBA name on the "Business name" line.

**Note.** You are requested to check the appropriate box for your status (individual/sole proprietor, corporation, etc.).

### Exempt From Backup Withholding

If you are exempt, enter your name as described above and check the appropriate box for your status, then check the "Exempt from backup withholding" box in the line following the business name, sign and date the form.

Generally, individuals (including sole proprietors) are not exempt from backup withholding. Corporations are exempt from backup withholding for certain payments, such as interest and dividends.

**Note.** If you are exempt from backup withholding, you should still complete this form to avoid possible erroneous backup withholding.

**Exempt payees.** Backup withholding is not required on any payments made to the following payees:

1. An organization exempt from tax under section 501(a), any IRA, or a custodial account under section 403(b)(7) if the account satisfies the requirements of section 401(f)(2),
2. The United States or any of its agencies or instrumentalities,
3. A state, the District of Columbia, a possession of the United States, or any of their political subdivisions or instrumentalities,
4. A foreign government or any of its political subdivisions, agencies, or instrumentalities, or
5. An international organization or any of its agencies or instrumentalities.

Other payees that may be exempt from backup withholding include:

6. A corporation,

7. A foreign central bank of issue,
8. A dealer in securities or commodities required to register in the United States, the District of Columbia, or a possession of the United States,
9. A futures commission merchant registered with the Commodity Futures Trading Commission,
10. A real estate investment trust,
11. An entity registered at all times during the tax year under the Investment Company Act of 1940,
12. A common trust fund operated by a bank under section 584(a),
13. A financial institution,
14. A middleman known in the investment community as a nominee or custodian, or
15. A trust exempt from tax under section 664 or described in section 4947.

The chart below shows types of payments that may be exempt from backup withholding. The chart applies to the exempt recipients listed above, 1 through 15.

IF the payment is for . . .	THEN the payment is exempt for . . .
Interest and dividend payments	All exempt recipients except for 9
Broker transactions	Exempt recipients 1 through 13. Also, a person registered under the Investment Advisers Act of 1940 who regularly acts as a broker
Barter exchange transactions and patronage dividends	Exempt recipients 1 through 5
Payments over \$600 required to be reported and direct sales over \$5,000 <sup>1</sup>	Generally, exempt recipients 1 through 7 <sup>2</sup>

<sup>1</sup>See Form 1099-MISC, Miscellaneous Income, and its instructions.

<sup>2</sup>However, the following payments made to a corporation (including gross proceeds paid to an attorney under section 6045(f), even if the attorney is a corporation) and reportable on Form 1099-MISC are not exempt from backup withholding: medical and health care payments, attorneys' fees; and payments for services paid by a Federal executive agency.

## Part I. Taxpayer Identification Number (TIN)

**Enter your TIN in the appropriate box.** If you are a resident alien and you do not have and are not eligible to get an SSN, your TIN is your IRS individual taxpayer identification number (ITIN). Enter it in the social security number box. If you do not have an ITIN, see *How to get a TIN* below.

If you are a sole proprietor and you have an EIN, you may enter either your SSN or EIN. However, the IRS prefers that you use your SSN.

If you are a single-owner LLC that is disregarded as an entity separate from its owner (see *Limited liability company (LLC)* on page 2), enter your SSN (or EIN, if you have one). If the LLC is a corporation, partnership, etc., enter the entity's EIN.

**Note.** See the chart on page 4 for further clarification of name and TIN combinations.

**How to get a TIN.** If you do not have a TIN, apply for one immediately. To apply for an SSN, get Form SS-5, Application for a Social Security Card, from your local Social Security Administration office or get this form online at [www.socialsecurity.gov/online/ss-5.pdf](http://www.socialsecurity.gov/online/ss-5.pdf). You may also get this form by calling 1-800-772-1213. Use Form W-7, Application for IRS Individual Taxpayer Identification Number, to apply for an ITIN, or Form SS-4, Application for Employer Identification Number, to apply for an EIN. You can apply for an EIN online by accessing the IRS website at [www.irs.gov/businesses/](http://www.irs.gov/businesses/) and clicking on Employer ID Numbers under Related Topics. You can get Forms W-7 and SS-4 from the IRS by visiting [www.irs.gov](http://www.irs.gov) or by calling 1-800-TAX-FORM (1-800-829-3676).

If you are asked to complete Form W-9 but do not have a TIN, write "Applied For" in the space for the TIN, sign and date the form, and give it to the requester. For interest and dividend payments, and certain payments made with respect to readily tradable instruments, generally you will have 60 days to get a TIN and give it to the requester before you are subject to backup withholding on payments. The 60-day rule does not apply to other types of payments. You will be subject to backup withholding on all such payments until you provide your TIN to the requester.

**Note.** Writing "Applied For" means that you have already applied for a TIN or that you intend to apply for one soon.

**Caution:** A disregarded domestic entity that has a foreign owner must use the appropriate Form W-8.

## Part II. Certification

To establish to the withholding agent that you are a U.S. person, or resident alien, sign Form W-9. You may be requested to sign by the withholding agent even if items 1, 4, and 5 below indicate otherwise.

For a joint account, only the person whose TIN is shown in Part I should sign (when required). Exempt recipients, see *Exempt From Backup Withholding* on page 2.

**Signature requirements.** Complete the certification as indicated in 1 through 5 below.

**1. Interest, dividend, and barter exchange accounts opened before 1984 and broker accounts considered active during 1983.** You must give your correct TIN, but you do not have to sign the certification.

**2. Interest, dividend, broker, and barter exchange accounts opened after 1983 and broker accounts considered inactive during 1983.** You must sign the certification or backup withholding will apply. If you are subject to backup withholding and you are merely providing your correct TIN to the requester, you must cross out item 2 in the certification before signing the form.

**3. Real estate transactions.** You must sign the certification. You may cross out item 2 of the certification.

**4. Other payments.** You must give your correct TIN, but you do not have to sign the certification unless you have been notified that you have previously given an incorrect TIN. "Other payments" include payments made in the course of the requester's trade or business for rents, royalties, goods (other than bills for merchandise), medical and health care services (including payments to corporations), payments to a nonemployee for services, payments to certain fishing boat crew members and fishermen, and gross proceeds paid to attorneys (including payments to corporations).

**5. Mortgage interest paid by you, acquisition or abandonment of secured property, cancellation of debt, qualified tuition program payments (under section 529), IRA, Coverdell ESA, Archer MSA or HSA contributions or distributions, and pension distributions.** You must give your correct TIN, but you do not have to sign the certification.

## What Name and Number To Give the Requester

For this type of account:	Give name and SSN of:
1. Individual	The individual
2. Two or more individuals (joint account)	The actual owner of the account or, if combined funds, the first individual on the account <sup>1</sup>
3. Custodian account of a minor (Uniform Gift to Minors Act)	The minor <sup>2</sup>
4. a. The usual revocable savings trust (grantor is also trustee)	The grantor-trustee <sup>1</sup>
b. So-called trust account that is not a legal or valid trust under state law	The actual owner <sup>1</sup>
5. Sole proprietorship or single-owner LLC	The owner <sup>3</sup>
For this type of account:	Give name and EIN of:
6. Sole proprietorship or single-owner LLC	The owner <sup>3</sup>
7. A valid trust, estate, or pension trust	Legal entity <sup>4</sup>
8. Corporate or LLC electing corporate status on Form 8832	The corporation
9. Association, club, religious, charitable, educational, or other tax-exempt organization	The organization
10. Partnership or multi-member LLC	The partnership
11. A broker or registered nominee	The broker or nominee
12. Account with the Department of Agriculture in the name of a public entity (such as a state or local government, school district, or prison) that receives agricultural program payments	The public entity

<sup>1</sup> List first and circle the name of the person whose number you furnish. If only one person on a joint account has an SSN, that person's number must be furnished.

<sup>2</sup> Circle the minor's name and furnish the minor's SSN.

<sup>3</sup> You must show your individual name and you may also enter your business or "DBA" name on the second name line. You may use either your SSN or EIN (if you have one). If you are a sole proprietor, IRS encourages you to use your SSN.

<sup>4</sup> List first and circle the name of the legal trust, estate, or pension trust. (Do not furnish the TIN of the personal representative or trustee unless the legal entity itself is not designated in the account title.)

**Note.** If no name is circled when more than one name is listed, the number will be considered to be that of the first name listed.

## Privacy Act Notice

Section 6109 of the Internal Revenue Code requires you to provide your correct TIN to persons who must file information returns with the IRS to report interest, dividends, and certain other income paid to you, mortgage interest you paid, the acquisition or abandonment of secured property, cancellation of debt, or contributions you made to an IRA, or Archer MSA or HSA. The IRS uses the numbers for identification purposes and to help verify the accuracy of your tax return. The IRS may also provide this information to the Department of Justice for civil and criminal litigation, and to cities, states, and the District of Columbia to carry out their tax laws. We may also disclose this information to other countries under a tax treaty, to federal and state agencies to enforce federal nontax criminal laws, or to federal law enforcement and intelligence agencies to combat terrorism.

You must provide your TIN whether or not you are required to file a tax return. Payers must generally withhold 28% of taxable interest, dividend, and certain other payments to a payee who does not give a TIN to a payer. Certain penalties may also apply.