

<b>Policy Name:</b> Industry Documents	<b>Policy Number:</b> 13.1
<b>Section:</b> Industry Relations – 13	<b>Date Revised:</b> March 15, 2013

## 13 Industry relations

The primary sponsor of Alliance studies is the National Cancer Institute, through research grants supporting these studies and the necessary infrastructure. However, Alliance also works with pharmaceutical companies and other health-related industry concerns to allow access to new investigational drugs or products that are relevant to Alliance research interests and to acquire financial support for unfunded or under-funded activities of the Alliance. Financial support, if acquired, helps to defray the costs of protocol development, implementation, data management, monitoring, patient tests that are not covered by insurance, laboratory studies, auditing, and statistical analysis.

Negotiations with industry are managed through the Alliance Chicago Office. Study chairs and committee chairs are not authorized to negotiate or sign agreements on behalf of Alliance.

The Federal principles governing industry collaborators in oncology trials are well established. The relationship is described in a document entitled “NCI – Cooperative Group – Industry Relationship Guidelines” (<http://ctep.cancer.gov/industryCollaborations2/guidelines.htm>) that focuses on manufacturer-NCI drug development agreements called Cooperative Research and Development Agreements (CRADAs) and Clinical Trials Agreements (CTAs). In addition, the NCI may distribute drugs for a network group trial under a Clinical Supply Agreement (CSA), independent of a CRADA or CTA. Many network group trials, however, involve drugs that are not the subject of such agreements, but the basic tenets of these agreements still apply to Alliance-industry collaborations.

### 13.1 Industry documents

Studies supported by pharmaceutical companies require a legal agreement in order for funding to be provided to the Alliance for Clinical Trials in Oncology Foundation, a tax-exempt nonprofit organization with the mission of supporting the research and educational programs of the Alliance. Other documentation, e.g., inclusion of standard language in the protocol document, and/or a letter of understanding from Alliance regarding drug or device/services provision, may be necessary for selected studies.

Examples of information included in each document are provided below.

#### 13.1.1 Legal agreement for provision of financial support

Description of funding to be provided, payment schedule, reporting requirements, data (if any) to be provided, advertising, termination, scope of work, and responsibilities of the parties. The parties to the legal agreement are the industry collaborator and the Foundation.

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### **13.1.2 Protocol document**

Standard language in the protocol document provided by NCI when drug is provided under a CRADA, CSA or CTA between the NCI and industry collaborator. The NCI language can be found in the document entitled “NCI Standard Protocol Language for Collaborative Agreements” (<http://ctep.cancer.gov/protocolDevelopment>).

Specific language in the protocol document may be required when drug is provided directly to the Alliance.

### **13.1.3 Letter of understanding regarding drug or device/services provision**

Reports summarizing the progress of active studies are generated by the Alliance Statistics and Data Center and distributed at the group meeting (at least annually). The summary also includes a listing of published manuscripts and abstracts. The primary purpose of these reports is to inform Alliance meeting attendees as well as the National Cancer Institute of the current status of Alliance research.

This letter, from the Alliance group chair, may discuss:

- Information regarding the structure and function of the Alliance
- Information regarding how the drug/device/service will be used/applied
- Information regarding the specific study for which the drug/device/service is provided
- Reference to the Alliance Policies and Procedures, as appropriate

<b>Policy Name:</b> Confidential and Proprietary Information	<b>Policy Number:</b> 13.2
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## **13.2 Confidential and proprietary information**

In studies involving collaboration with the pharmaceutical industry, it is the responsibility of all institutional participants to maintain confidentiality with regard to proprietary, trade secret, or other confidential information. Confidential and proprietary industry information is strongly discouraged from inclusion in study protocol document.

All study chairs must abide by group policy that requires strict confidentiality of study information (see section 6). The Alliance statistician carries out all interim analyses in a confidential manner. No one other than those explicitly authorized to be part of the monitoring process has access to the results. All such persons must keep all aspects of their deliberations in strict confidence until the release of results is approved. Any violation of confidentiality is considered a serious offense.

<b>Policy Name:</b> Data Ownership in the Context of Industry Collaboration	<b>Policy Number:</b> 13.3
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### **13.3 Data ownership in the context of industry collaboration**

Pursuant to NCI policy, the Alliance owns all data resulting from its trials. It is willing to provide accrual updates, copies of adverse event reports, regulatory documents, and study summaries to industry collaborators. If a collaborator wishes trial results or regulatory information to use for internal or regulatory purposes, the appropriate terms can be negotiated. Typically this requires a legal agreement. If a trial involves two or more investigational drugs, each company must normally consent to all data being provided to the other company/ies.

<b>Policy Name:</b> Release of Data	<b>Policy Number:</b> 13.4
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### **13.4 Release of data**

Trial data may be made available to industry collaborators pursuant to executed agreements for data transfer. The data resulting from Alliance studies (except for adverse events reports and other data as mentioned in section 13.3) should be available to industry collaborators within six months of data maturity for primary endpoint, as long as funding is available for such endeavor. Confidential data under active monitoring by the DSMB are not released without the approval of the Alliance DSMB. Industry collaborator requests for data are managed by the Alliance Chicago office.

<b>Policy Name:</b> Indemnification	<b>Policy Number:</b> 13.5
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### **13.5 Indemnification**

The Alliance and its Foundation are not liable for any acts or omissions of the industry collaborator with respect to the conduct of Alliance studies. The Alliance requests that the collaborator indemnify all investigators against loss under customary product liability principles, including responsibility for drug information in the Investigator’s Brochure. Because it lacks the legal power to do so (i.e., because it is not a legal entity), the Alliance is not in a position to indemnify collaborators or manufacturers against claims due to negligence of its members.

<b>Policy Name:</b> Intellectual Property and Patent Rights	<b>Policy Number:</b> 13.6
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### **13.6 Intellectual property and patent rights**

An invention resulting from work performed by an Alliance investigator generally is the property of either the investigator or the Alliance institution with which he or she is affiliated. It is the policy of the Alliance that investigators shall disclose to the Alliance group chair any inventions or discoveries, whether patentable or not, resulting from Alliance studies (aka “Intellectual Property”) in writing within ninety (90) days of discovery thereof. Upon receipt of the notification, the group chair, along with the investigator(s), will consider the appropriate institutional officials to participate in a meeting to discuss matters of recognition and remuneration related to the patenting, licensing, exploitation or commercialization of the Intellectual Property. It is not the intent of this policy to interfere with the publication of research results.

The Alliance has a contractual relationship with each of its member institutions that requires adherence to this policy and all policies described in the Alliance Policies and Procedures. *In addition*, the provisions in the NCI “Intellectual Property Option to Collaborator” ([http://ctep.cancer.gov/industryCollaborations2/intellectual\\_property.htm](http://ctep.cancer.gov/industryCollaborations2/intellectual_property.htm)) terms of award modifications apply to Alliance studies using investigational agents.

<b>Policy Name:</b> Publication of Study Results	<b>Policy Number:</b> 13.7
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### **13.7 Publication of study results**

Consistent with the traditional principle of academic freedom, the right of the public to know about government-funded trial results, and the policy of major medical journals, the Alliance requires that its investigators have the absolute right to publish all study results. At least thirty days before submission of a manuscript for publication, a copy is provided to the industry collaborator for advisory review and comment, so that the manufacturer can protect patent opportunities and review for disclosure of proprietary information. See NCI Standard Protocol Language for Collaborative Agreements (<http://ctep.cancer.gov/industryCollaborations2>). If patent-related action is necessary, an additional sixty-day delay is provided.

<b>Policy Name:</b> Use of Agent/Device Provided by Industry Collaborator	<b>Policy Number:</b> 13.8
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### **13.8 Use of agent/device provided by industry collaborator**

Any agent/device provided by an industry collaborator may not be used by participating institutions and investigators for any purpose outside the scope of the protocol. Neither the institution nor the investigator may charge any third party payer or patient enrolled in the study for the agent/device, and the institution or investigator may not include the cost of such agent/device in any cost report to third party payers.