National Cancer Institute Common Issues in Gift Agreements

Overview: This document identifies some of the more common issues that emerge in gift agreements and related gift documents that the National Cancer Institute (NCI) receives from donors. In addition to the issues identified below, NCI addresses other less common issues that we encounter in gift agreements on a case-by-case basis.

We hope this document will serve as a helpful guide to explain the issues that NCI often encounters and how NCI addresses them. However, this document does not serve as a replacement for the gift review process or the NIH Policy Manual Chapter 1135 on Gift Administration (see below for details). And, while this document is designed to cover many common issues that NCI encounters in gift agreements, it is not an exhaustive list.

Introductory Note: As we explain below, only NCI – not an individual NCI researcher – may accept a gift of funds to support NCI research. However, donor gift agreements, including applications for grants or other donations to support research conducted by an NCI Principal Investigator (PI), often ask that the NCI PI sign the application for funding or sign the gift agreement document.

Where a donor requires a signature by a PI on these documents, including during the application phase of the process, NCI will advise the PI to sign as acknowledging the content of the documents, rather than signing as the authorized individual to accept the gift. A designated NCI official will sign as the authorized party.

Gift Agreements – Common Issues

A. NCI Review of Agreements that Accompany Gifts: Donors often submit agreements, memoranda of understanding (MOUs), or similar documents associated with a proposed gift. These may be accompanied by or refer to exhibits, attachments, terms and conditions, or other documents.

NCI Divisions and the Office of the Director must carefully review, and where necessary edit these documents, consistent with the laws, regulations, and policies that govern NCI. NCI performs this review in consultation with the Office of General Counsel. Once NCI and a donor settle on a satisfactory agreement, the NCI Ethics Office must also review the gift and any gift conditions.

B. Document Format: NCI can conduct a more timely and efficient review of a donor's documents if we receive copies of all documents in the MS Word format.

C. Gifts vs Grants: Donors sometimes use the term "grant" in agreements they propose. For example, the donor may refer to their donation as a "grant" when the donor is providing a conditional gift to support a research program or project. Regardless of whether a donor uses the term "gift" or "grant" in an agreement, NCI accepts the monetary and non-monetary support as an unconditional or conditional gift under the statutory gift authorities. Therefore, NCI uses the term "gift" to refer to this support. The legal authorities for NCI to accept gifts appear in sections 231, 405(b)(1)(I), and 497 of the Public Health Service (PHS) Act, as amended (42 U.S.C. §§238, 284(b)(1)(I), and 289f).

The National Institutes of Health (NIH) issued the Policy Manual Chapter 1135 – Gifts Administration¹ to implement the statutory and delegated authorities for gifts. NCI relies on Manual Chapter 1135 throughout the gift process.

D. Other Legal Authority: In addition to the gift authority, many other legal authorities may apply to the research that NCI conducts with support from a donor, and to the agreements that often accompany a donor's gift. Examples of the broad categories of legal authority include –

- 1. Human subject protection
- 2. Animals used in research
- 3. Publishing research results
- 4. Data sharing
- 5. Scientific misconduct or other misconduct or performance by NCI employees
- 6. Donor's access to documents related to the research
- 7. Intellectual property that results from the research
- 8. The confidentiality of research and research results
- 9. The applicability of state, local, or foreign laws to NCI.

Some of these legal authorities and a discussion of how NCI addresses potential conflicts with these authorities appear in the sections below. In general, where NCI identifies a potential for conflict between what appears in the donor's proposed gift agreement and the laws, regulations, and policies that apply to NCI, NCI will revise the gift agreement and, where necessary, add conditions stating, for example, that requirements identified above are, "subject to applicable laws, regulations, and policies."

NCI may also address conflicts between NCI legal authorities and a proposed gift agreement by including text such as the following:

[Insert the name of the donor] acknowledges that -

1. [NCI] accepts the gift or grant funds identified in this [insert the title of the agreement and list any documents associated with the agreement], hereafter collectively referred to as "agreement documents," with the mutual

¹ NIH Policy Manual Chapter 1135 is found at <u>https://policymanual.nih.gov/1135</u>.

understanding that the funds will be expended in the manner required by the agreement documents only to the extent that doing so is consistent with applicable federal laws, regulations, and policies of the NIH.

2. In the event of a conflict between the agreement documents and applicable federal laws, regulations, and policies of the NIH, the applicable federal laws, regulations, and policies of the NIH will govern in all cases. With respect to this gift of funds or grant by [insert the name of the donor], examples where federal laws, regulations, and policies of the NIH will govern in lieu of anything to the contrary in the agreement documents include, but are not limited to, [identify specific paragraphs in the agreement and any documents associated with the agreement that are inconsistent with federal laws, regulations, and policies of NIH].

E. Role of NCI; Role of NCI Researcher: Proposed gift agreements that NCI receives from donors often suggest roles and responsibilities for an NCI researcher serving as the lead or principal investigator for the research. However, section C of NIH Policy Manual Chapter 1135 states, "Gifts to support activities of individual employees may be accepted only if the principal beneficiary of the gift is the NIH rather than the employee, and the gift is given in such a form that the money can be used even if the employee leaves NIH." To summarize this feature of Manual Chapter 1135, only NIH and NCI, not the NCI researcher, can accept a gift to support NCI research.

With this requirement in mind, NCI will delete text in gift agreements that identifies an NCI researcher as the responsible party and insert language that identifies NCI as the responsible party. The same is true on the signature page where the official that NCI designates, not the researcher, must appear as the responsible party. If necessary, the NCI researcher can sign the agreement in a form that acknowledges that the researcher has read the gift agreement. In addition, NCI will either modify or delete text in agreements that purports to condition the availability of the gift on the researcher's employment at NIH, based on the requirements of Manual Chapter 1135.

F. Supplementing Salaries: Under NIH Policy Manual Chapter 1135, gifts cannot be used to support or supplement the salary of a current permanent NCI employee. NCI will delete text that conflicts with this restriction. Gift funds can be used for other non-salary research costs and activities, and to support research fellows and other individuals that NCI does not employ on a permanent basis.

G. NCI Financial Commitments in the Context of Gifts: Gift agreements sometimes request NCI to commit funding to the research or activity supported by the gift. Based on current law (section 231 of the PHS Act) and the NIH Policy Manual Chapter 1135, NCI may not accept a gift that is conditioned upon any expenditure that cannot be made from the gift itself or from the income of the gift. NCI will delete text in agreements that require or request an NCI financial commitment.

H. Future Financial Commitments and the Antideficiency Act: The Antideficiency Act [31 U.S.C § 1341 (a)(1)] prohibits a federal agency from making a commitment in advance or in excess of the agency's appropriation. Issues related to the Antideficiency Act can arise in many ways in gift agreements. One example is a gift agreement that seeks to require NCI to commit to funding research in the future. Another example is indemnification language that attempts to require that NCI hold the donor harmless from future costs, losses, expenses, or claims that may arise due to the research or other activity.

NCI cannot make commitments that conflict with the Antideficiency Act, and NCI will either modify or delete text in a gift agreement that conflicts with this statute.

I. Insurance: Gift agreements often ask that NCI obtain insurance against losses. Generally, as an agency of the federal government, NCI self-insures. An explanation of this issue can be found in the GAO's Principles of Appropriations Law, Chapter 4, page 175 (2018 edition). The link to this volume is http://www.gao.gov/special.pubs/d04261sp.pdf. NCI will delete text requiring NCI to maintain insurance.

J. Segregated Account: Gift agreements often request that NCI establish a separate, segregated account for the gift funds. NCI has an account in the U.S. Treasury where NCI must deposit gift funds.

K. Return of Funds: Gift agreements often identify situations that require the return of gift funds. These situations can include a remaining balance at the end of the research period or a remaining balance if the research is terminated. Gift agreements often refer to "un-spent" or "uncommitted" funds to describe these situations.

However, the technical federal budget term for such situations is "unobligated" gift funding. NCI will substitute the term "unobligated" in these situations.

L. Use of Name or Logos: Like many institutions, NCI monitors and protects the use of its name by others. To address this concern, NCI includes the following language in agreements with donors:

Donors or their affiliates may not use, encourage others to use, or facilitate others to use the logos, a likeness of the logos, or other trademarks or service marks belonging to NCI, NIH, or HHS. Such use is prohibited unless and until the terms of such use are agreed upon in separate written agreement between the NCI, NIH, or HHS, as applicable, and the donor and the use is in accordance with applicable law, regulations, and policies.

M. Endorsement: As an agency of the Federal government, NCI does not make endorsements and cannot be perceived as endorsing a donor, its products, services, or activities. To address this concern, NCI includes the following language in agreements with donors:

Nothing in this agreement may be interpreted to imply that the United States, the Department of Health and Human Services, the National Institutes of Health or the National Cancer Institute endorses the donor, its products, services, or activities. The donor will not take any action or make any statement that suggests or implies such an endorsement.

N. Governing Law: Donors often insert text into agreements suggesting that the law of the state where they primarily operate will govern in the event of any dispute. Because NCI is a federal agency, federal law must govern any interpretation of an agreement, not state law. Where necessary, NCI will modify agreements to state that federal law will govern in the event of a dispute.

O. Dispute Resolution: The U.S. Department of Justice represents federal agencies in litigation and in doing so, makes litigation decisions on behalf of agencies. Therefore, NCI generally will not accept provisions in an agreement that require specific types of dispute resolution in advance of litigation or that acknowledge any rights or remedies that a party may have related to litigation, including, for example, injunctive relief. NCI will delete such text where it appears. However, NCI can accept language stating that each party intends to engage in good faith efforts to resolve a dispute in a timely manner through negotiations with the other party.

P. Physician Payments Sunshine Act: Section 6002 of the Affordable Care Act established a program to identify the financial relationships between drug and device manufacturers and certain health care providers. Donors often assume that reporting under the Physician Payments Sunshine Act applies to the NCI researcher that will lead the scientific research on behalf of NCI.

However, as we explain in the Introductory Note and in paragraph E, NCI – not an NCI researcher – accepts a gift of funds to conduct research. As a consequence, it is NCI's understanding that it is not a "covered recipient" under the Physician Payments Sunshine Act. Therefore, NCI will delete or revise language in gift agreements related to the Physician Payments Sunshine Act.

Q. Acknowledging Support: NCI recommends the following text to acknowledge support: "Where possible, all research papers, releases, or exhibits directly related to the research supported by this gift shall include a statement such as: *'This research was supported by funding from [INSERT NAME].'"*

R. Intellectual Property and Royalties Policies: Donors frequently insert language or refer to donor requirements on intellectual property rights. Federal laws, regulations and NIH policies do not permit NCI to give license options or share royalties with a donor pursuant to a gift agreement. NCI will delete such language where it appears.

S. Liability: Donors often insert language imposing liability on NCI for damages arising under the research. NCI will modify language in the gift agreement to address restrictions discussed in section H of this document on the Antideficiency Act and other U.S. laws relating to the government's liability, including the Federal Tort Claims Act [28 U.S.C. § 2671, et seq].