#5

1166 NCI POLICY ON JOINT ENDEAVORS WITH COMMERCIAL ORGANIZATIONS

A. Purpose: This manual chapter implements NIH Instruction and Information (I&I) Memorandum OD 84-2, Principles and Guidelines for Joint Ventures with Commercial Organizations in the Support of NIH Activities by establishing the NCI policy on joint endeavors with commercial firms.

B. Applicability: The policy and procedures outlined in this chapter apply to any and all joint endeavors between commercial firms and NCI program elements or staff.

C. References: NIH I&I Memorandum OD 84-2, Principles and Guidelines for Joint Ventures with Commercial Organizations in the Support of NIH Activities.

D. Responsibility:

1. Assistant Secretary for Health (ASH) - must approve all joint endeavors which involve any type of disposition of the government's rights (i.e. patent rights, exclusive license, assignment of rights) to inventions.

2. Office of the General Counsel (OGC), NIH - will answer any questions about any legal issues that may arise in conjunction with collaboration with the commercial sector. Matters involving any disposition of the government's rights to inventions may be referred to the NIH Patent Attorney and the NIH Patent Board.

3. Executive Committee NCI - will review and approve all proposed agreements for joint endeavors except those in the form of contracts, grants or cooperative agreements. The Director, NCI will sign those agreements that must be forwarded to ASH for approval.

4. Division Director, NCI - will review draft agreements for joint endeavors originating in his or her Division and sign all agreements after review and approval by the Executive Committee except those requiring approval by ASH.

5. Investigator, NCI - will usually act as initiating agent in the process of entering into collaboration with a commercial firm, its employee(s) or representative(s) by developing a preliminary plan and submitting it in the form of a draft proposal to his or her Division Director for review an approval through

the cognizant Laboratory or Branch Chief and whatever other internal reviewers that Divisional policy may require.

E. Definitions:

1. COMMERCIAL SECTOR -- Includes any for-profit corporation, firm or individual (e.g. - private companies, drug or device manufacturers, insurance companies, etc.). The term specifically excludes nonprofit organizations such as philanthropic or non-profit institutions and universities.

2. SPONSOR -- Any agency or organization that contributes resources to another organization for the purposes of conducting a project, performing an activity or staging an event.

3. RESOURCES -- Includes: (1) funds to support a project; (2) personnel to participate in the joint project; (3) services in support of the project; (4) facilities, equipment, and technologies that are utilized in the conduct of the project; (5) materials or supplies that are consumed in the course of the project; (6) contributions of ideas, suggestions or data.

4. PERFORMER -- a participating member in the joint endeavor who jointly or singly conducts the project utilizing the resources provided by sponsors, its own internal resources, or both. A performer might be: (1) an NCI staff member or organizational component; (2) a member of the commercial sector; (3) any other organization.

5. MECHANISM OF SUPPORT -- The type of method or instrument used to specify the amount of support and to define the terms and conditions of the agreement to participate in a joint endeavor.

6. JOINT ENDEAVOR -- any event, project or activity in which there is joint participation by the NCI and the commercial sector. In order to be considered a joint endeavor, a collaboration must have all of the following characteristics:

   a. entry into the collaborative relationship must be intentional and deliberate. In the case of a conference, the NCI and the commercial organization must both be active

organizers for a collaboration to exist. The provision of resources alone, one to the other or both to a third party, does not, of and in itself, constitute a collaboration. If a situation arises in which the NCI and a commercial sector participant wish to collaborate on a joint research project project and, for reasons of administrative convenience, one of the parties channels its contribution to the project through a third party (e.g. FAES) or other conduit, the collaboration would meet this criterion because the intent of the relationship is collaboration regardless of the means used to transfer funds or other resources.

Of course, any direct collaboration between the NCI and a member of the commercial sector is presumed to be intentional and deliberate.

b. one of the performers/sponsors must be a member or representative of a for-profit organization or an individual entrepreneur.

c. NCI and/or commercial sector participant must contribute resources to the collaborative activity.

d. collaboration with a commercial sector participant must have as its purpose the conduct of research; the exchange of research information/technology transfer; or research product or process development. Excluded from the definition of a joint endeavor are any business relationships established to furnish supplies or equipment to the government or to provide planning, analytical, logistical, administrative support or other consultative or staff services.

Informal and sporadic contacts between NCI staff and members of the commercial sector to exchange ideas or provide small amounts of relatively inexpensive resources (e.g. reagents, cell lines or other research material) do not constitute joint endeavors and, therefore, are not subject to the policy contained in this manual chapter. However, repeated informal contacts should be examined and reported if the prolonged and repeated nature of the contacts, when taken as a whole, constitute a de facto collaborative agreement with the commercial sector.

Donations from the commercial sector to the NCI Unconditional Gift Fund would not be reportable because they involve no

collaboration between the donor and the recipient in a mutually agreed upon project and they are, by definition, free from any and all conditions.

Similarly, a Guest Researcher suported by an FAES fellowship, where funds may have been donated to the FAES by a commercial organization, is not reportable when there is no collaborative understanding or placement of conditions on the use of the donation. Conversely, a Guest Researcher supported under conditions described in paragraph 6.a. above would be reportable on the basis that the Guest Researcher is a participant in a mutually ageed upon collaboration between the NCI and the commercial sector donor.

F. Policy: It is NCI policy to support and foster collaborative efforts which will assist in the attainment of the research goals of the Institute with all segments of the scientific community including the commercial sector.

All agreements for joint endeavors which will include at least one commercial sector participant must be reduced to writing and signed by all participants to protect the rights and integrity of all parties involved. In most cases, such agreements will be in the form of contracts, grants or cooperative agreements between the commercial sector participant and the NCI but they may take the form of formal letters of agreement (see Illustration I).

G. General Principles and Guidelines: Because commercial firms have a different orientation and motivation than non-profit and academic institutions, there are certain factors that should be kept in mind by anyone contemplating entering into a collaborative project with a commercial firm. They are:

1. Research Priorities and Program Relevance - Joint endeavors should be entered into only when the purpose of the collaboration is fully compatible with the research mission of the NCI and the participation of the commercial sector participant will enhance the possibility for successful attainment of the project's goals. The availability of outside sources of project funding should not affect the decision to enter into a research collaboration with a commercial firm.

2. Scientific Quality and Integrity of the Project - The NCI should do all that it can to ensure that the usual high standards of scientific project performance are not compromised.

This is not meant to imply that the commercial sector generally tolerates or adheres to lower standards of performance than other segments of the research community but their needs and priorities do not always coincide entirely with ours and this could result in differing opinions on how a project should be conducted and research results reported. This being the case, NCI staff should take appropriate measures to assure that adequate agreements are developed that minimize the possibility for misunderstandings about each participant's expectations of the project and each other.

3. Institutional Integrity and Conflict of Interest - In any joint endeavor with the commercial sector, there is the danger that the participation of the NCI in the project could be exploited commercial gain through advertising or claim or appearance of official endorsement of the NCI/government of a commercial product. NCI employees should be sensitive to this possibility and make every effort to preclude its occurrence through careful wording of the written agreement with the commercial sector participant and diligent monitoring of their activity.

4. Dissemination of Scientific Information - One area that may be particularly troublesome when dealing with the commercial sector is that of reaching mutual agreement on when and in what form scientific information describing the joint endeavor is to be released. The NCI has an obligation as a member of the research community and as mandated by its authorizing legislation to disclose and disseminate research results both nationally and internationally. This obligation may sometimes conflict with the desire on the part of the commercial sector participant to assure its competitive position in the marketplace by beating its competitors to the punch in product or process development while guarding against disclosure of trade secrets and other proprietary information. This potential clash of conflicting interests can best be resolved through negotiation and translation of the results of the negotiation into a carefully worded written agreement between the principals on the disclosure of research information.

Additional guidance on this subject is contained in Section E. of NIH Instruction and Information Memorandum (I&I) OD 84-2 dated 10/19/84.

In most cases, collaborative agreements between the NCI and the commercial sector will be in the form of contracts, grants and cooperative agreements which are prepared and negotiated by specialists and should reflect existing policy and procedures in the subject areas

discussed above. Other formats for collaborative arrangements such as Formal Letters of Agreement require additional care in their formulation because they are done less frequently and without the amount of staff assistance and policy guidance that accompanies contracts, grants and cooperative agreements. A guide for the preparation of Formal Letters of Agreement is attached as Illustration I. Procedures on the development and approval process for joint endeavors is contained in the section that follows.

H. Procedures

1. The NCI staff member and the prospective commercial sector collaborator begin preliminary discussions about the possibility of a joint endeavor. The NCI staff member discusses the possibility of a joint endeavor with his or her Program Director and/or Division Director and receives permission to proceed with the preparation of a draft agreement following the guidelines contained in this Manual Issuance and NIH I&I OD 84-2 on the same subject.

2. The draft agreement is reviewed by the cognizant Program Director and Division Director for soundness of scientific approach, compatibility with Divisional and Institute mission, research priority, financial feasibility, legal ramifications and conformity with policy. If the draft is found to be acceptable, it is given preliminary approval at the Division level and the initiator may proceed with the development of the agreement.

3. If the agreement will be in the form of a contract, grant or cooperative agreement, the Research Contracts Branch or the Grants Administration Branch, NCI will see to it that the appropriate clauses are contained in the instrument of agreement and the appropriate people review and approve the agreement. NCI officials planning an agreement for a joint endeavor in the form of a contract, grant or copperative agreement will follow established policies and procedures applicable to these mechanisms of support and need not submit draft agreements to the Director, NCI or the Executive Committee for review and approval.

4. If the agreement will be in the form of a Formal Letter of Agreement rather than a contract, grant or cooperative agreement and, if the agreement will involve some disposition of the government's rights to inventions (i.e. patent rights, exclusive license, assignment of rights, etc.), a copy of the

draft and a written request for review is sent to the Office of the General Counsel, NIH. The initiator will wait for the written response from the OGC before proceeding.

If the Formal Letter of Agreement does not involve any disposition of the government's rights to inventions, Divisional officials have the discretionary authority to decide whether the draft agreement should be reviewed by the OGC or not.

5. After completion of internal and/or OGC review, the proposed agreement is sent to the Executive Committee, NCI for review and approval.

6. After review and approval by the Executive Committee, the agreement will be either signed by the Director, NCI, if it involves any assignment of the government's rights to inventions, or signed by the cognizant Division Director if it does not involve disposition of the government's rights to inventions. Once signed by the Division Director, the agreement can be forwarded to the commercial firm for execution.

7. If the agreement does involve disposition of the government's rights to inventions, the agreement must be sent to the Assistant Secretary for Health (ASH) for approval. After receiving ASH's approval, the agreement may be sent to the commercial firm for signature.

8. If the agreement is not in the form of a contract, grant or cooperative agreement, after execution by all parties to the agreement, a Report of NIH-Profit Sector Joint Endeavor (see Illustration II) should be completed and sent the Administrative Officer for the Program in which the agreement originated for inclusion in the annual inventory which will occur in October of each year and will cover the previous fiscal year. Agreements with the commercial sector in the form of contracts, grants and cooperative agreements will be reported centrally. Divisional Administrative Officers will be asked to verify the information collected on contracts, grants and cooperative agreements and add reports on other formal agreements with the commercial sector entered into during the previous fiscal year. Reports from the various Divisions will be collected, consolidated into an Institute report and forwarded to NIH.

I. Additional Information The NCI contact person for matters relating to joint endeavors with the commercial sector is the Director of Staff Operations, Office of the Director. Questions on the contents of the policy issuance itself should be directed to the Management Analysis Branch, Office of the Director, NCI.

#6

FOUNDATION FOR ADVANCED EDUCATION IN THE SCIENCES

FAES Program for Administration of Grants

General Information and Instructions

The FAES Board of Directors has established a program to administer grants of funds from outside sources for the support of research and training at the NIH. Such grants have in the past served primarily to support research fellows in NIH laboratories, but they may be used to support any research or training activity appropriate to the purposes of the NIH and of the FAES. A Grants Committee has been appointed to oversee the program and to review and approve requests to the FAES by NIH sponsors for the administration of such grants.

Such grants may include funds to pay stipends for one or more fellows, salaries and fringe benefits of employees, supplies, equipment, travel, books, and tuition. In order to offset the expenses of administering grants, FAES requires that a 5 per cent management fee be added to each grant budget. If the donor states in writing that its policy prohibits payment of a management fee, the grants committee will consider accepting the grant with a waiver of the management fee.

A sponsor who wishes the FAES to administer a proposed grant must make application to the FAES on the appropriate form. FAES application Form F is for use when the funds are intended solely for the support of a specific, designated Fellow, including stipend. Application Form G is used for all other purposes.

Before a formal request for funds is sent to a prospective donor, the sponsor (or principal investigator) must submit it together with either Form F or Form G to the FAES so that the Grants Committee can review it. The Grants Committee will normally approve such requests if:

(a) the activity to be supported is consistent with the purposes of the NIH and of the FAES,

(b) the grant application requests funds for the obligatory fringe benefits of proposed staff if indicated,

(c) the grant applicant requests a 5% management fee, and

(d) the proposal has been approved by the Institute's Scientific Director.

Renewal applications must be handled in the same way.

Information on specific budget items will be found in the attached instructions for Forms F and G.

Other policies and guidelines include the following:

(1) The FAES will do all the bookkeeping for the grants it administers, maintain all financial records, and submit financial statements to donors as requested.

(2) Unless other arrangements are made, stipends and salaries will be paid by the FAES directly to the recipients on the last working day of each month. Instructions for other arrangements for payment of stipends and salaries or for other kinds of expenditures should be submitted to the FAES directly by the sponsor with sufficient documentation to support the request for payment.

(3) It is the responsibility of sponsors to complete the NIH Guest Worker form for all recipients of grant-supported stipends and salaries.

(4) The FAES will not administer a grant of funds where any aspect of the management cannot be made public.

Attachment

12/4/81

FAES Program for
Administration of Grants

Specific Instructions for Form F
(Stipends and Other Support for Fellows)

1. Three copies of Form F and one copy of the grant application prepared for the prospective donor must be submitted to the Executive Secretary of the FAES, Mrs. Lois Kochanski, Building 10, Room B1-L-101.

2. A separate Form F must be completed for each Fellow.

3. The FAES administers a group health insurance plan which is available to all Guest Researchers at NIH. (See "Employee Benefits" page for costs.) It should be noted that foreign Guest Researchers are required by NIH to have health insurance. Sponsors may wish to include a request for such funds in their applications to donors.

4. To offset the cost to FAES of administering grants, the FAES requires a management fee of 5 per cent of the total grant, and prospective donors must be asked for such funds. If a donor states in writing that his policy prohibits the payment of such fees, the FAES will consider a request for a waiver of this requirement.

5. All lines on Form F must be filled in with the requested information or by the abbreviation "n.a." (not applicable.)

6. Before coming on duty, all foreign nationals must have their passport examined by the Executive Secretary of FAES.

Revised 7/26/83

Form F

REQUEST TO FAES FOR ADMINISTRATION OF FELLOWSHIP

(use this form only if recipient is to be a FELLOW)

Date: _____

Donor: _____
(organization or person awarding fellowship)

Recipient:

Name _____

Highest Degree _____ Institution _____ Year _____

Citizenship _____

Resident Alien _____ or Nonresident Alien _____

Registration # _____ or Passport # _____

Visa category and expiration date _____

Date of Initiation _____ Date of Termination _____

Stipend: $ _____

Other Funds: _____

(such as travel, tuition, books)

Health Insurance Premium: _____

Subtotal: _____

Management Fee (5% of Subtotal): _____

Total Amount: $ _____

Sponsor:

Name _____

NIH designation _____

NIH address _____ NIH Phone No. _____

I certify that the recipient of these funds will be primarily in training.

Signature _____ Date _____

Scientific Director:

Name _____

Signature _____ Date _____

FAES Recording: _____ Date _____
Mrs. Lois W. Kocnanski, Exec. Secretary

FAES Grants Committee Approval:

_____ Date _____
Dr. John C. Ebernart, Chairman

_____ Date _____
Dr. Alan Peterkorsky

_____ Date _____
Dr. Edward Kuff

12/4/31

FAES Program for
Administration of Grants

Employee Benefits

REQUIRED FOR FOREIGN GUEST RESEARCHERS; OPTIONAL FOR OTHER GUEST RESEARCHERS

Hospital Insurance Premiums per Month

	Low Option	High Option
Individual	$50.00	$63.00
Family	$118.00	$171.00

REQUIRED FOR EMPLOYEES:

- FICA (Social Security) - 7.05% of salary from donor (max. salary
  - 7.05% of salary from employee $39,600)
- Maryland Unemployment Insurance - 3.1% of 1st $7,000 per year from donor
- Workmens Compensation - 0.60% of salary from donor

Revised 1/1/85

FAES Program for
Administration of Grants

Specific Instructions for Form G
(Grant Application)

1. Three copies of Form G and one copy of the grant application prepared for the prospective donor must be submitted to the Executive Secretary of the FAES, Mrs. Lois W. Kochanski, Building 10, Room B1-L-101.

2. In order to provide required benefits for employees being paid from a grant, the FAES will serve as the employer of record for those staff members who will be providing a service (as opposed to Fellows, who are in training.) The benefits in question are Social Security (Soc. Sec.), Maryland Unemployment Insurance, and Workmens Compensation. A list of current rates is attached. The application to the donor must contain budgetary items to pay these costs.

3. The FAES administers a group health insurance plan which is available to all Guest Researchers at NIH. (See "Employee Benefits" page for costs.) Foreign Guest Researchers are required by NIH to have health insurance. Sponsors may wish to include a request for such funds in their applications to donors.

4. To offset the cost to FAES of administering grants, the FAES requires a management fee of 5 per cent of the total grant, and prospective donors must be asked for such funds. If a donor states in writing that his policy prohibits the payment of such fees, the FAES will consider a request for a waiver for this requirement.

5. In the case of a grant in which the identity of a staff member and/or the salary amount have changed or were not specified in the original application, the request for the payment shall originate with the sponsor on Form F and be signed by the Scientific Director.

6. All lines on Form G must be filled in with the requested information or by the abbreviation "n.a." (not applicable.)

7. All foreign nationals must complete the first nine lines of Form F. Before coming on duty, all such individuals must have their passports examined by the Executive Secretary of FAES. It should be noted that individuals holding J-1 visas are exempt from Social Security payments. Those individuals holding J-2 visas whose employment is authorized by the appropriate I-94 and individuals holding F-1 student visas, which can include 12 months of work, should be covered by Social Security. All support personnel will be covered by Maryland Unemployment Insurance and Workmens Compensation Insurance.

Revised 7/26/83

Form G

REQUEST TO FAES FOR ADMINISTRATION OF GRANT

(use this form if funds are for other than Fellows)

Date: _____

Donor: _____

Title of Grant or purpose: _____

Principal Investigator (sponsor) _____

NIH designation _____

NIH address _____ NIH Phone No. _____

Date of Grant Initiation _____ Date of Grant Termination _____

Budget — Amount Requested

Personnel Name (if known) and Title	Citizen-ship	Salary	Soc. Sec.	MD Unemol.	Wkms. Comp.	Totals

Equipment: . . . . . $_____

Supplies: . . . . . _____

Travel: . . . . . _____

Health Insurance: . . . . . _____

Other Expenses: . . . . . _____

Subtotal: . . . . . _____

Management Fee (5% of subtotal): . . . . . _____

Total to be sent by donor: . . . . . $_____

Signature of sponsor _____ Date _____

Scientific Director:

Name _____

Signature _____ Date _____

FAES Recording: _____ Date _____

Mrs. Lois W. Kochanski, Exec. Secretary

FAES Grants Committee Approval:

_____ Date _____

Dr. John C. Ebernart, Chairman

_____ Date _____

Dr. Alan Peterkofsky

_____ Date _____

Dr. [illegible]

12/9/81

Lab & Branch Chiefs

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

RELEASE DATE

#1

MANUAL TRANSMITTAL SHEET

SUBJECT

2300-735-4 OUTSIDE WORK AND ACTIVITIES

1. Explanation of Material Transmitted: This chapter provides guidelines on outside work and activities, describes in somewhat more detail than in the past the issues that govern the approvability of requests to do outside work, and includes additional changes for clarity.

   a. Substantive additions to the guidelines are provisions relating to:

      (1) New criteria for consultative service to industry.

      (2) Acceptance of honoraria by the incumbents of certain NIH positions.

      (3) Conditions under which private medical and dental practice may be permitted.

   * b. Deletion of the requirement for a renewal Form HHS-520, Request for Approval of Outside Activity, for continuing activities where neither the position of the employee nor the activity has changed since the initial approval. } ?

2. Material Superseded: None.

3. Filing Instructions: File in NIH Manual Series 2300 or Federal Personnel Manual Chapter 735. Holders of the Federal Personnel Manual should file the transmittal sheet in the NIH Manual as a cross-reference.

Remove	Insert
None	2300-735-4 (dated 8/1/85)

Consulting for Universities?

Distribution

F-401
F-403
F-405

2300-735-4 OUTSIDE WORK AND ACTIVITIES

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2300-735-4 OUTSIDE WORK AND ACTIVITIES

A. Purpose and Scope This chapter states the policies and guidelines which govern outside work and activities requiring approval above the level of the BID Director and prescribes the procedures for obtaining approval. Requests which may be approved within the BID are described in NIH Manual 1130 Delegations of Authority, Personnel No. 16.

Comprehensive regulations on outside work applying to all HHS employees are contained in the HHS Standards of Conduct, 45 Code of Federal Regulations Part 73 (Standards). This NIH Manual chapter interprets, supplements and is subordinate to the Standards but does address items of particular interest to NIH. A copy of the Standards, concerning outside activities, is found in Appendix 1.

This chapter applies to all NIH Civil Service and Commissioned Corps employees. It does not apply to NIH staff who are not "employees," such as guest researchers, visiting fellows, and members of initial review groups (grants, contracts and cooperative agreements) and special government employees. This chapter does apply to visiting associates and visiting scientists as they are considered to be NIH employees.

B. Background and References

1. Background The last official NIH statement on the issues of outside work by NIH staff members was the 1970 NIH Manual chapter entitled "Outside Work and Other Outside Activities," subsequently deleted in 1978. A revised chapter was prepared in 1974, but it was never issued. Several specific problems were dealt with in NIH Instruction and Information Memoranda or minutes of the Board of Scientific Directors.

   A Committee on Outside Work was appointed by the Director, NIH, in 1982 because of: the elapsed time since the last comprehensive statement; new issues raised by requests from biotechnology companies for consulting by NIH scientists; the desire of some scientists to accept such invitations; and, in part, the perceived need for additional guidance for NIH officials with authority to recommend or approve outside activities.

   The Committee recommendations were approved by the Board of Scientific Directors, the BID Directors, and the Director, NIH.

   Executive Order 11222, Section 202, provides the federal policy on outside work: "An employee shall not engage in any outside employment, including teaching, lecturing, or writing, which might result in a conflict, or an apparent conflict, between the private interests of the employee and his official government duties and responsibilities, although such teaching, lecturing, and writing by

employees are generally to be encouraged so long as the laws, the provisions of this order, and Office of Personnel Management and agency regulations covering conflict of interest and outside employment are observed."

2. References The authority of the Director, NIH, to formulate and issue policy on outside work and activities is 45 CFR §73.735-708(a)(4). Other related references are:

   a. Executive Order 11222
   b. Federal Personnel Manual Chapter 735
   c. 45 CFR §73.735-701 et. seq.; HHS Personnel Instruction 735-1
   d. CC Personnel Manual Chapter CC 26, Subchapter CC 26.1c
   e. NIH Manual 1130, Delegations of Authority, - Personnel No. 16, Outside Activities or Work and Statements of Employment and Financial Interests

C. Responsibilities The Director, NIH, reserves the authority to issue policy and procedures concerning outside activities. Any BID supplementation must receive prior approval of the Director, NIH. Officials with authority concerning outside work and activities are listed in NIH Manual 1130, Personnel No. 16.

1. Recommending and Approving Officials (See NIH Manual 1130, Delegations of Authority) are responsible for:

   a. reviewing each Form HHS-520 and appraising it on the basis of the Standards, and all other applicable laws, regulations, or internal rules of the PHS or NIH;

   b. consulting with the NIH Legal Advisor in all cases that raise a difficult or novel question of law or fact;

   c. examining the propriety of the Form HHS-520, using their knowledge of the intricacies of the responsibilities of the employee and the relationship of the proposed activity to NIH programs;

   d. assuring that any relationship of the activity to NIH programs or responsibilities, or any official relationship with other agencies, organizations, or individuals is disclosed on the Form HHS-520;

   e. communicating disposition of the Form HHS-520 in writing.

2. Recruitment and Employee Benefits Branch (REBB), Division of Personnel Management (DPM) is responsible for:

a. reviewing each Form HHS-520 and Form HHS-521 for compliance with statutory, regulatory and NIH requirements;

b. obtaining additional information from initiating BID or outside source to clarify conflict issues, identifying precedent cases, and recommending approval/disapproval on those Forms HHS-520 requiring disposition within the Office of the Director;

c. providing assistance to supervisors, BID Outside Work Contacts/Personnel Officers, recommending and approving officials;

d. requesting the Form HHS-521, in July of each year, on all continuing outside work or activities; reviewing Form HHS-521 for discrepancies between the reported information and the information in Form HHS-520 on which approval was based. If a discrepancy is indicated, REBB forwards the matter to the approving official for review and disposition;

e. preparing a statistical summary of the year's activities and reporting emerging trends or problems to the Director, NIH;

f. maintaining copies of Form HHS-520 approval/disapprovals and Form HHS-521.

3. BID Outside Work Contact/Personnel Officer is responsible for:

a. reviewing each Form HHS-520 for conformance to procedural requirements; accuracy and completeness, and forwarding to REBB for processing;

b. requesting annually, Forms HHS-521 from each employee who received approval for a continuing outside work or activity, comparing reports to requests, reconciling inconsistencies and forwarding Forms HHS-521 to REBB by October 1 of each year;

c. requesting renewals of Form HHS-520s where necessary.

4. Supervisors are responsible for:

a. acquiring a working knowledge of pertinent statutes, regulations, policies, and procedures regarding outside work;

b. helping their employees understand requirements;

c. assuring that program-related considerations are disclosed on the Form HHS-520.

2300-735-4 OUTSIDE WORK AND ACTIVITIES

5. Employees are responsible for:

   a. acquiring a working knowledge of the DHHS Standards of Conduct and of PHS and NIH policies regarding outside work;

   b. submitting Form HHS-520 when required (see H below);

   c. providing complete information on the Form HHS-520 and attaching additional material if necessary;

   d. initiating a revised Form HHS-520 for all continuing activities if they change positions or if there is a change in the activity;

   e. submitting the required Forms HHS-521 by September 10 of each year to the BID Outside Work Contact/Personnel Officer;

   f. obtaining advice and assistance from supervisors, and/or BID Outside Work Contacts/Personnel Officers when needed.

D. Relationship to the HHS Standards of Conduct This chapter is interpretive of the Department's Standards of Conduct. In all cases, proposed activities must be permissible under the Standards in order to be approved by NIH. Interpretation and application of the Standards have taken into account the role of the NIH in the broad support of biomedical research and training throughout the United States and the NIH programs in patient care. For these reasons requirements of this chapter are in some instances more restrictive than those of the Standards. The following paragraphs summarize some of the provisions of the Standards and their implications.

The Department's Standards of Conduct permit employees to engage in certain types of outside activities. The provisions of the Standards relating to outside activities apply to all HHS employees except for special Government employees, and apply whether an employee is on leave, including leave without pay, or on or off duty. All employees should be familiar with these regulations (45 CFR Part 73). Before an employee may engage in specified types of outside activities, advance administrative approval must be obtained. The categories of activities for which advance administrative approval is required under the Standards are as follows:

- Certain writing or editing activities [see 45 CFR §73.735-705(d)];

- Certain types of teaching [see 45 CFR §73.735-706(b)];

- All professional and consultative services;
- Any other outside activity for which the head of an Operating Division of HHS (OPDIV) (PHS, for example) or the head of an OPDIV subunit (NIH, for example) imposes internal requirements for administrative approval; and
- Certain office-holding activities in professional societies [see 45 CFR §73.735-707(b)].

Requests for advance approval are initiated by submitting Form HHS- 520, Request for Approval of Outside Activity (see Illustration 1). The request should clearly and completely describe the nature of the proposed activity, and how it is compatible with the Standards of Conduct.

The Standards further provide that in reviewing requests for approval of outside activities, the approving official shall appraise each request on the basis of the Standards, and "all other applicable laws, regulations, or internal rules" of the PHS or NIH.

E. Guidelines to Employees and NIH Officials Who Recommend or Approve Outside Work In general, previous NIH policies continue. A major exception is consulting for industry. Although it had been previous policy to disapprove such requests, consulting is now permissible under certain circumstances. This change recognizes: the increasing desire of NIH scientists to consult for nongovernmental for-profit organizations that are engaged in biomedical research, the increasing importance of these organizations in contemporary biomedical research, Executive Branch encouragement of closer governmental/private sector cooperation, and the belief that conflict of interest problems can be avoided if the safeguards in this chapter are followed.

Employees should be familiar with all of the outside work guidelines and determine which pertain to them. Certain requirements, such as those governing consulting with industry, apply to all NIH employees. Others apply only to extramural program administrators. An extramural program administrator who wishes to consult for industry must satisfy both sets of requirements.

NIH employees should be aware of and sensitive to activities that may be inappropriate because of the potential for embarrassment to NIH, HHS, or the Federal Government. For example, in certain circumstances, because of an NIH employee's professional credentials, a nongovernmental party may seek to retain the employee to testify as an expert witness at a trial or similar forum. This should be avoided when the subject is highly controversial and the general public is likely to attribute the

employee's views to NIH. (Note that NIH employees are subject to a formal PHS policy restricting testimony in private litigation as part of official duties. See NIH Manual Chapter 1171.) (Also see E-9 below.)

1. Basic Requirements For All Employees In all cases of proposed outside activity, the BID should first determine whether or not the activity should be authorized as official business with NIH paying the travel and other expenses, if any. Only activities other than official business are controlled by this chapter.

   Each NIH employee is expected to so regulate any outside activities as not to interfere with performance on the job or constitute a real or apparent conflict with job requirements. All responsibilities must be so organized that NIH time or facilities will not be committed (e.g., the employee will be on annual leave). No NIH employee should engage in any outside activity which would:

   - Constitute a real or apparent conflict of interest;
   - Tend to damage the NIH appearance of objectivity in the eyes of the biomedical community, particularly those organizations whose products are tested by NIH or with which NIH participates through grants, cooperative agreements or contracts;
   - Interfere with an employee's regularly assigned duties. "Regularly assigned duties" include the total set of obligations and responsibilities which characterize the performance of professional researchers and research administrators at the NIH.

   The employee is initially responsible for avoiding such activities. When there is doubt in an employee's mind about the propriety of contemplated activities, he or she should consult with the supervisor before undertaking the proposed outside activity. In any case where there is doubt or where the contemplated outside activity involves professional performance or other activities for which advance approval must be sought under 45 CFR Part 73 and this policy, Form HHS-520 should be submitted to the employee's supervisor.

   Some NIH officials hold positions of such national prominence that most of their proposed outside work activity could reasonably be considered to fall within their official responsibilities for which they are already being compensated. There are, however, some activities outside the scope of their official duties for which remuneration can be accepted. Details are contained in E.3 below.

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Some NIH officials hold positions that appear to enable them to influence a grant, cooperative agreement or contract award. They may not accept an honorarium for any outside work activity from an institution or organization that has recently negotiated, or in the near future may be expected to seek, a grant, cooperative agreement or contract from NIH.

Official NIH travel funds may not be authorized for travel related to outside work. When participating in an official role, it is preferable to travel on official travel funds. On occasion (defined by the travel regulations) it may be proper to accept payment from an outside institution, in lieu of Government funds, for travel expenses when the visit is on official business.

2. Profession-Oriented Activities of NIH Employees The NIH requires each employee to submit a Form HHS-520 to the employee's supervisor for approval before engaging in outside activities which require the use of professional qualifications readily identified with NIH employment.

   Activities subject to this requirement include private medical and dental practice, consultative services, teaching and lecturing, and the acceptance of awards or any form of compensation from a "for-profit" organization. Each request will be judged against the basic requirements criteria listed above and on individual merits. The requirements of individual NIH assignments vary sufficiently so that outside work appropriate for an employee in one assignment may not be appropriate in another assignment.

3. Teaching, Lecturing, and Speechmaking Teaching, lecturing, and speechmaking activities, with or without remuneration, are recognized as beneficial to NIH and to staff members who are so engaged. Employees may participate in these activities with prior approval, provided the conditions set forth in the Standards of Conduct (§73.735-706) are met.

   By statute, an honorarium for any one article, appearance or lecture is limited to a maximum of $2,000, excluding amounts for actual travel and subsistence expenses for the employee and his/her spouse (2 U.S.C. 441i). The term "honorarium" means payment of money or other thing of value whether made gratuitously or as a fee for an appearance, speech, or article, but does not include salary or compensation made for services rendered on a continuing basis, such as for teaching, or as proceeds from the sale of a book or similar undertaking. (See Section 4.b below for limits on lecturing for industry.)

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4. Consulting and Lecturing for Industry

* a. Consulting for Industry Both NIH employees and approving officials should recognize that consulting for industry raises special concerns. "Industry," in this case, means a for-profit firm or a non-profit organization which seeks to develop and/or market, directly or indirectly, a technique, process or product. The possibility exists that an employee will be tempted to alter the direction of research activities in order to benefit the company for which consulting is performed. In addition, the more time spent in outside consulting and the more compensation received, the greater is the potential for conflict of interest or adverse effect on the employee's official NIH responsibilities.

The following requirements apply to consultations for industry:

- Consulting work that utilizes the general knowledge and expertise of the employee may be approved to be performed on an ongoing basis for a particular individual, company or institution. However, information concerning the employee's ongoing NIH research should be available on a non-exclusive basis, through, for example, lectures such as those presented at an open conference.

- Outside consultation with private industry for compensation requires the approval of the Director, NIH.

- Total compensation from consulting is limited to $25,000 per year, with no more than $12,500 from any individual company. Compensation may not include stock options, nor may the employee own stock in the company for which he/she consults. The amount of compensation is required to be listed on Form HHS-520 under item 11: "Method or Basis of Compensation." 2K?

- No service on a Board of Directors is permitted.

- No government time, facilities, or other resources may be used.

- A company cannot list the name of the NIH scientist or his/her affiliation with the NIH in material used for publicity or promotional purposes.

- If outside consulting work is to be performed during normal NIH working hours, the NIH employee must be on annual leave or leave-without-pay and not present at the employee's ?

normal duty station. (Commissioned Officers are required to take one day of annual leave for each day during which any consulting takes place.)

- A tentative contract between the employee and the proposed outside employer is to accompany the application for approval, Form HHS-520, for such work. (A copy of any signed contract is to be sent to the Division of Personnel Management, Office of Administration.) The proposed contract should include statements on the following:

  - The number of work days per year.

  - A stipulation that the work will not interfere in any way with the employee's responsibilities at NIH; that the work will be done on annual leave or leave-without-pay from NIH; that the employer will have no proprietary interest in any work that the employee has done or will do at NIH; that the employee will not disclose any information derived from work at the NIH until it has been disclosed publicly, either in a written publication or in an oral presentation at a lecture or meeting which is open to the public and that has been publicly announced; and that the employer will not refer, in anything distributed for publicity or product promotion, to the employee's affiliation with NIH.

  - The method and amount of compensation for the employee's services and expenses.

  - The employee's obligation to report certain inventions made by the employee to the Government. The following language is recommended:

    "Notwithstanding any other provision in this agreement, the consultant shall not be restricted from reporting an invention made by the consultant (whether alone or jointly) to the Department of Health and Human Services (HHS) as required by Federal

regulations at 45 CFR Part 7.* Nor shall anything in the agreement restrict or preclude the ability of HHS to ascertain its rights in such an invention."

- The employee may agree not to divulge to other parties confidential information provided by the employer.

- Exclusive contracts (i.e., contracts in which the employee agrees not to consult with any other company) may not be signed.

Interactions with a particular company on unpublished or undisclosed NIH research should only be carried out under a collaborative agreement as part of the employee's official duties.

Some examples of consulting activities that would not be approved include:

- Consulting for a company that has applied for or received a research contract with the employee's own BID.

- Consulting to assist a company in the preparation of grant applications, contract or cooperative agreement proposals, or project reports to be submitted to any part of the Federal Government, with the exception that such activity can be approved if it is intended that the employee is to be named as principal investigator. Then the provisions of section G of this Chapter and of NIH Manual Chapter 4204 apply.

- Consulting for a company whose products are leased or purchased by the NIH, when the employee has a role in such acquisitions that could lead to a conflict of interest. The DHHS Standards of Conduct prohibit an employee from participating in a decision, e.g., the decision to lease or purchase equipment, involving organizations in which the employee has a financial interest, such as a consultative relationship with the company.

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*Those regulations require the reporting of any invention made by an HHS employee that bears any relation to his/her official duties, or that was made in whole or in part during working hours, or with any contribution of Government facilities, equipment, material, funds, or information or of time or services of other Government employees on official duty.

- Consulting for a company if the official position of the employee is likely to be used to promote a product or service, or to imply an official point of view or action of the Department.

b. Lecturing for Industry Lectures of an open nature, in an industry-sponsored forum, are permitted subject to the statutory limitation on maximum remuneration per instance of $2,000 with the added limitations of no more than $12,500 from any one company per year, and a maximum of $25,000 from lectures to industry in any one year.

Lect. to Unio

5. Outside Work by High Level NIH Officials, Particularly BID Directors Outside work on the part of high level NIH officials may, under certain circumstances, be permissible. It must be recognized, however, that some high level NIH officials (NIH Director, Deputy Directors, and Associate Directors; BID Directors and Deputy Directors) hold positions of such national prominence that most potential outside work opportunities could reasonably be considered to fall within their official responsibilities. These officials must be circumspect about engaging in outside work for remuneration in order to avoid causing embarrassment to NIH or creating a real or apparent conflict of interest. There are occasions, however, when they can separate themselves from their official role and accept remuneration. It must also be remembered that many high level officials participate in the awarding of grants, contracts and cooperative agreements and therefore will be restricted from accepting remuneration from those recipients of federal financial assistance or from persons, institutions or organizations potentially falling into these categories. With these restrictions in mind, the following types of work are examples of permissible outside activities provided they are permissible under the DHHS Standards of Conduct and are approved in advance in accordance with this policy.

- Writing or editing scientific material for publication.

- Lecturing at national or international symposia or conferences, when such lectures concern the employee's recognized area of professional expertise and do not pertain to his/her official responsibilities.

- Participating in a committee for selecting recipients of awards or prizes.

- Teaching, lecturing, or participating in the preparation of examinations for nonprofit professional societies such as the American Board of Internal Medicine.

- Serving as a lecturer sponsored by a private endowment that is not connected with or controlled by an institution or person receiving grants, contracts or cooperative agreements.

Approval for all remunerated outside activities comes from the Director, NIH. In the event of disapproval of a proposed activity, the high level official may request that the Director, NIH, seek an advisory opinion from an appeals committee composed of the three NIH Deputy Directors.

6. Outside Work by Extramural Program Administrators No major change has been made from the previous policy that generally restricted outside work for remuneration by extramural program administrators, because of their responsibilities for grant, cooperative agreement or contract review or administration.

In many ways, extramural program staff are similar to BID Directors and other high level NIH officials. Because of their role in making or influencing funding decisions, extramural staff must be considered separately from intramural scientific or general administrative staff. Thus an extramural administrator cannot tacitly be assumed to be free to give the commencement address at his/her alma mater, for example, and to receive an honorarium. It would be inappropriate to do so if that institution is, or is likely to be, a recipient of NIH funds.

A useful approach in determining whether a given outside activity is appropriate or not is to consider the following five characteristics.

a. Nature of the Group or Agency Associated with the Outside Work In most instances, the nature of the work sponsor will be the paramount consideration for extramural program administrators. Opportunities for outside work at institutions that are actual or potential recipients of NIH financial support should, in general, be declined. This would exclude most major non-profit organizations such as universities, research institutions, etc. The exclusion extends also to profit-making organizations that are eligible for grants, cooperative agreements or contracts. The exclusion might also extend to a variety of voluntary agencies that, from time to time, receive NIH financial support. In particular, it almost always is inappropriate to receive an honorarium from such an organization.

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An extramural employee may accept an invitation to serve as an officer of a learned society or a professional or scholarly organization. He/she must secure advance approval if (a) the organization has or is seeking a grant or contract with the employee's Bureau, Institute, or Division, or (b) the organization is one which customarily expresses publicly views on matters of legislative or administrative policy within the specific areas of concern to the Department. Thus, for these societies and organizations, the guidelines for both extramural and intramural employees are the same.

In some circumstances it may be important to judge whether the extramural employee can be isolated from further NIH decisions involving the inviting organization. Thus, currently, the outside employer may have no NIH support and it may seem unlikely that it ever will. If that situation changes in the future, it may be advisable to divorce the staff member from any determinative role in funding decisions.

b. Nature of the Responsibilities of the Individual Extramural Staff Member There is, to some extent, a hierarchy of potential conflicts based upon the individual's precise role and influence in making funding decisions. Thus, a somewhat higher degree of sensitivity should exist for award-making program staff as compared with an employee who is working entirely in program planning and evaluation. Executive secretaries of initial review groups may be viewed as occupying a somewhat intermediate position.

c. Nature of the Outside Activity Assuming the outside work request is consistent with the factors concerning the nature of outside organization and the functions of the employee, (a and b above) judgment must next progress to this assessment. Individual circumstances of the request need to be judged. Some types of outside work are more readily justified than others. For example, scholarly writing, editing, and publishing are allowable. Similarly, an extramural administrator may serve on a prize committee that is evaluating individuals for awards based upon past accomplishments. Such evaluations and recommendations are primarily retrospective. On the other hand, service on search committees and review panels that are related to the broad area of biomedicine may be inappropriate, whether with or without compensation.

d. Nature of the Topic Even if the proposed outside work does not relate to the employee's current activities at NIH, there may be reason for disapproval. The outside work activity may be

related to professional activities that the staff member was engaged in prior to joining NIH, or may relate to activities that are outside biomedicine (e.g., the arts), but the activity may be proscribed if the inviting agency is a current or potential recipient of NIH funds. This serves to emphasize the overriding importance of the first factor, "The Nature of the Group or Agency Associated with the Outside Work."

e. Nature of the Compensation The size and type of compensation must also be considered and both qualitative and quantitative factors deserve consideration. Compensation may involve a cash fee or honorarium or an award, honor, or prize (recognition and prestige have value), travel funds, housing, or provision for other costs and expenses. There are, of course, activities that will be considered impermissible whether or not compensation is provided.

7. Outside Work by Intramural Scientists Serving as Contract Project Officers An NIH intramural scientist serving as a contract project officer may accept compensation from an institution only if the official duties of the scientist, as a contract project officer, are not related to that institution. For example, any lecture delivered to an institution to which the official duties of the scientist, as a contract project officer, are related, must be on "official duty" with all expenses paid by the NIH. If that intramural scientist is invited by a department (not institution) which has no contract relationship with him/her but does receive BID contract funds, the scientist may not accept an honorarium, but may deliver a lecture to that department on "official duty" status. The scientist may ordinarily receive, on behalf of the government, travel expenses and/or per diem in payment-in-kind (if approved on Form HHS-348, Request and Approval for Acceptance of Payment of Travel Expenses in Cash or in Kind. See NIH Manual 1500).

   An NIH intramural scientist contract project officer may accept an invitation by a department of an institution in which a different department receives a BID contract so long as the scientist, as a contract project officer, has no relationship with the institution. Use Form HHS-520 for this request. He/she may also deliver a lecture to that department, as an "outside activity," and receive an honorarium, travel expense, and per diem allowance for hotel, meals, etc., with these expenses being paid by the requesting department.

8. Service to Contract, Cooperative Agreement or Grant-Assisted Projects Remuneration may not be accepted for service of any kind to a PHS contract, cooperative agreement or grant-assisted project. This policy does not automatically preclude remunerated or other

service to an organization in its institutional capacity when some part of the organization is receiving a contract or grant. It does, however, preclude service to any specifically identified contract, cooperative agreement, or grant-assisted project of such an organization.

For example, if a university receiving a PHS contract, cooperative agreement, or grant for a specific project requests the services of an NIH staff member for such project, the service may be authorized only as part of official duties.

However, if the requested service is for some other project of the university which is not assisted by a PHS contract, cooperative agreement, or grant, this limitation does not apply as long as the service does not include participating in applying for a PHS contract, cooperative agreement, or grant.

In fact, all NIH employees must be extremely careful in even providing information about possible contracts as, under the Federal Acquisition Regulations, providing unequal assistance to potential contractors can have serious consequences.

It is important that this policy be understood by those arranging for or recommending approval of outside work. An official who initiates a request for approval of service for which there will be remuneration must ascertain and state whether or not the proposed remuneration is derived in whole or in part from a PHS contract, cooperative agreement or grant.

9. Clinical Practice Private clinical practice may be requested on Form HHS-520 and is generally permitted, if on one's own time, subject to administrative restrictions. It is generally limited to a maximum of 8 hours per week (400 hours per year). Each employee requesting authority to engage in the private practice of medicine must agree that:

   - No patient, with whom a continuing physician-patient relationship is established in outside private practice, will be referred to the NIH as either an in-patient or out-patient as a consequence of that relationship;

   - The employee will never knowingly establish a physician-patient relationship in outside private practice with any current or recently discharged NIH patient; and

   - No employee with final responsibility for the admission of patients to the Clinical Center may receive a fee for service as

a consultant to another physician where the condition of the patient would appear to make the patient eligible for Clinical Center admission in an area currently supervised by that employee.

Furthermore, an NIH employee should not accept a primary responsibility for the care of one or more patients except in circumstances where it will clearly not impose on, or interfere with, his/her responsibilities as a Federal employee.

10. Outside Work Involving Testimony in Private Litigation

PHS policy on testimony in private litigation is found in NIH Manual 1171. That chapter does not cover testimony in an employee's private capacity.

The controversial nature of some private litigation and the sensitivity of the issues that may be involved have already been mentioned. For example, if such testimony would necessarily involve using the names or patient records of former NIH patients, the employee would have to testify in his/her official capacity in accordance with NIH Manual Chapter 1171. For these reasons each employee requesting outside work approval involving testimony in private litigation must agree that:

- No NIH information or data will be used that has not yet been published.
- No present or former NIH patient names or patient records will be used.
- If the case involves a patient seen at NIH, the employee will disqualify him/herself.
- Any opinion rendered will be his/her own personal opinion and not that of NIH or the Department, and
- The subject of the litigation is not controversial and is not likely to become controversial in the future.

The Director, NIH, retains authority to approve requests for participation in litigation as an outside activity if the Government is likely to be a party to the litigation, is likely to request leave to serve as a friend of the court, or is known to have a substantial interest in the litigation. Consultation with the Office of the General Counsel must precede such approval. Authority to disapprove

such requests is delegated to Deputy and Associate Directors of NIH, and BID Directors, in their respective areas.

F. Use of Leave in Outside Work Approved outside work and activities must be undertaken outside of officially scheduled work hours or during periods of approved leave. In the case of Commissioned Officers, station leave may not be used for outside work, and annual leave must be taken in whole days rather than in hours.

G. Conditions Governing Work on a Grant Application or a Contract Proposal Naming an NIH Intramural Scientist as Principal Investigator An NIH intramural research scientist, while still an NIH employee, may, under certain conditions, develop plans for research and similar projects and prepare grant applications or contract proposals to be submitted by a non-Federal institution or organization to NIH or other Federal agencies for consideration for funding. The employee may be named as the proposed principal investigator. The conditions are quite specific and must be adhered to in order to avoid violation of the DHHS Standards of Conduct and Federal conflict of interest statutes. This subject is fully covered in NIH Manual Chapter 4204 to which any interested employee should refer.

H. Procedural Requirements

1. Initial Approval

a. Before commencing any outside activity requiring advance administrative approval, an employee must obtain that approval by initiating a Form HHS-520, Request for Approval of Outside Activity. For supplemental material which will assist employees in providing necessary information see I.2 below, Preparation of Requests. The Form HHS-520 should be initiated well ahead of anticipated commencement of the activity. Recommending and approving officials are specified in NIH Manual 1130, Delegations of Authority.

b. Recommending officials are responsible for establishing routing and copy requirements for Forms HHS-520 under their authority. All Forms HHS-520 must be routed through the REBB for review (original and one copy).

c. Forms HHS-520 should reach the REBB at least two weeks before the proposed activity is to begin. A reasonable effort will be made to review late requests so that they are approved prior to the performance of the activity. REBB recommends disposition to the appropriate approving official.

d. After approval/disapproval, the original request is returned to the REBB for forwarding through the BID to the employee. The REBB will retain a copy of the approval/disapproval and maintain the official file of Forms HHS-520.

e. Renewals of continuing activities (e.g., private practice) must be submitted if the employee changes positions or if there is a change in the activity.

2. Annual Report

a. Each person performing a continuing activity (versus a one-time activity) must file a Form HHS-521 by September 10 of each year for the prior 12 months.

b. The original Form HHS-521 is to be submitted to the REBB, where it will be reviewed for discrepancies between the reported information and the information in the Form HHS-520 on which approval was based. Discrepancies will be brought to the attention of the approving official for review and disposition. The Form HHS-521 is retained by REBB with the approval copy of Form HHS-520 in accordance with the Privacy Act and other requirements.

I. Preparation, Routing, and Approval of Requests

1. Outside Work and Activities Requiring Approval

The following outside activities require advance approval:

a. Teaching, lecturing, and speech making.

b. Professional and consultative services with outside organizations.

c. Private medical and dental practice.

d. Consultative service relating to patient care.

e. Service on boards or committees.

f. Writing, editing, or publishing.

g. Holding office in a professional organization.

h. Any outside work or activity by an NIH employee, in his/her Government capacity or otherwise, which creates a real or

apparent conflict of interest or about the propriety of which the employee is uncertain.

i. Any other outside activity for which the Director, NIH, imposes an approval requirement through an amendment to this manual chapter.

2. Preparation of Requests All requests are made by submitting Form HHS-520, Request for Approval of Outside Activity to the employee's supervisor. To avoid delays in processing requests and possible complications from failure to obtain approval prior to commitment to participate in an outside activity, give special attention to completing the following items on the form:

Requesting Employee

→ Item 7. Indicate "Nature of Activity" according to the categories listed under section I.1 (Outside Work and Activities Requiring Approval) or other topic titles found in this chapter. For teaching and lecturing give title of course or lecture. For writing and editing give title of chapter, book, or journal, and add the following statement: "The Department's requirements with regard to writing and editing done not as part of official business will be observed."

→ Item 8c. If answer is "no" show how absence will be accounted for during official duty hours. Hours/days of absence from work in 8c. must agree with 8a. "period covered." If employee is departing after work hours or returning before or during work hours, please so indicate.

→ Item 11. List the method and amount of compensation for any proposed consultation with industry.

Reviewing Official

Item 18c. Indicate title of approving official.

3. Approving Officials Officials authorized to approve requests are specified in NIH Manual 1130 Delegations of Authority - Personnel No. 16.

4. Annual Report By September 10 each year each employee for whom a continuing outside work has been approved during the past year must report the items shown in 45 CFR §73.735-709 (shown in Appendix 1)

using Form HHS-521 "Annual Report of Outside Activity," shown in Illustration 2.

J. Information and Supply of Form HHS-520 Further information and copies of Form HHS-520 may be obtained from BID personnel offices.

K. Additional Copies of this Chapter For extra copies of this chapter, send a Form NIH-414-5, Request for NIH Manual Chapter, to the Printing and Reproduction Branch, Division of Administrative Services, Building 31, Room B3BE07.

REQUEST FOR APPROVAL OF OUTSIDE ACTIVITY

(Ref. HHS Personnel Guides for Supervisors, Chapter IV, Guide 7, Supplement 1)

☐ Initial Request
☐ Revised Request
☐ Renewal

NOTE TO EMPLOYEE: See Information on Reverse Side of This Form

1. NAME *(Last, First, Initial)*	2. ORGANIZATIONAL LOCATION *(Principal Operating Component, Bureau, Division)*
3. TITLE OF POSITION	4. GRADE AND SALARY *(Federal)*
*5. NAME, ADDRESS AND BUSINESS OF PERSON OR ORGANIZATION FOR WHOM OUTSIDE SERVICES WILL BE PERFORMED	6. LOCATION WHERE SERVICES WILL BE PERFORMED

7. NATURE OF ACTIVITY *(Indicate type of activity, e.g., teaching, consultative services, and give full description of specific duties or services to be performed. Specify, when possible, the scheduled days of week and hours of day proposed activity will be performed.)*

8. ESTIMATED TIME INVOLVED

a. PERIOD COVERED FROM TO	b. ESTIMATED TOTAL TIME DEVOTED TO ACTIVITY *(If on a continuing basis, give estimated time per year)*

c. WILL WORK BE PERFORMED ENTIRELY OUTSIDE USUAL WORKING HOURS?

☐ YES ☐ NO IF NO, INDICATE ESTIMATED NUMBER OF HOURS OR DAYS OF ABSENCE FROM WORK

9. DO YOUR OFFICIAL DUTIES RELATE IN ANY WAY TO THE PROPOSED ACTIVITY?

☐ NO ☐ YES *(Describe)*

*10. IF PROVIDING CONSULTATIVE OR PROFESSIONAL SERVICES, ARE YOUR WOULD-BE ASSOCIATES RECEIVING OR WILL THEY SEEK, A GRANT OR CONTRACT FROM A FEDERAL AGENCY?

☐ NO ☐ YES *(Describe)*

11. METHOD OR BASIS OF COMPENSATION	12. WILL COMPENSATION BE DERIVED FROM A DHEW GRANT OR CONTRACT?
☐ FEE ☐ HONORARIUM ☐ PER DIEM ☐ PER ANNUM ☐ ROYALTY ☐ EXPENSES ☐ OTHER *(Specify)*	☐ NO ☐ YES *(Describe)*

13. THIS REQUEST IS MADE WITH FULL KNOWLEDGE OF DEPARTMENT AND PRINCIPAL OPERATING COMPONENT POLICY AND PROCEDURES ON OUTSIDE ACTIVITIES. THE STATEMENTS I HAVE MADE ARE TRUE, COMPLETE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF.

14. SIGNATURE OF EMPLOYEE	15. DATE	*16. ADDITIONAL INFORMATION ATTACHED ☐ YES ☐ NO

*17. ACTION RECOMMENDED

a. ☐ APPROVAL ☐ DISAPPROVAL	b. SIGNATURE	c. TITLE	d. DATE

18. ACTION TAKEN

a. ☐ APPROVAL *☐ DISAPPROVAL	b. SIGNATURE	c. TITLE	d. DATE

*See reverse of form

HHS-520 (Rev. 8/81)

ANNUAL REPORT OF OUTSIDE ACTIVITY

(Ref.: HHS Personnel Guides for Supervisors, Chapter IV, Guide 7, Supplement 1)

NOTE TO EMPLOYEE: See Information on Reverse Side of This Form

SECTION I

TO:	1. EMPLOYEE'S NAME, TITLE, GRADE, AND SALARY	2. DATE
FROM:	3. APPROVING OFFICIAL	4. REPORT PERIOD ENDING August 31,_____

Each person for whom an approval for outside work is currently on record is required to file an annual report. It will be necessary, therefore, for you to complete and return this form to me through regular channels within 15 days of the date shown in item 2.

SECTION II - PRECEDING 12 MONTHS

5. NATURE OF APPROVED ACTIVITY	6. ACTIVITY PERFORMED FOR *(Person or organization and address)*

7. WAS THE ACTIVITY ACTUALLY PERFORMED?

☐ YES ☐ NO If "No", explain

8. AMOUNT OF TIME SPENT ON ACTIVITY *(Specify hours worked)*	9. HAS THERE BEEN ANY CHANGE WITH RESPECT TO INFORMATION, OTHER THAN SHOWN IN ITEM 8, ON WHICH APPROVAL WAS BASED? *(If "Yes", a revised request must be submitted)* ☐ YES ☐ NO

SECTION III - NEXT 12 MONTHS

10. DO YOU ANTICIPATE THAT THE ABOVE ACTIVITY WILL CONTINUE?

☐ YES ☐ NO

11. DO YOU ANTICIPATE ANY CHANGE WITH RESPECT TO INFORMATION PREVIOUSLY FURNISHED *(If "Yes", a revised request must be submitted)*

☐ YES ☐ NO

12. DO YOU WANT YOUR REQUEST FOR APPROVAL OF OUTSIDE ACTIVITY CANCELLED?

☐ YES ☐ NO *If "Yes", indicate date* _____

13. SIGNATURE OF EMPLOYEE	14. DATE
15. REVIEWED BY	16. DATE OF REVIEW

17. COMMENTS *(Continue on reverse, if necessary)*

☐ SEE REVERSE, IF CHECKED

HHS-521 (Rev. 7/81)

CONSULTING AGREEMENT WITH INDUSTRIAL ORGANIZATION

#8A

Agreement between
Industrial Organization (I.O.): _____

_____

of (City & State): _____ and

National Cancer Institute (NCI) Employee: _____

This contract relates to consulting work proposed by an Outside Employer identified above as the Industrial Organization, and the above named NCI Employee, identified herein as the Consultant. An Industrial Organization shall mean in this Agreement a for-profit firm or a non-profit organization which seeks to develop and/or market, directly or indirectly, a technique, process or product.

The following items are agreed to by both the I.O. and the Consultant:

1. The proposed work will not interfere in any way with the Consultant's responsibilities at the NIH, and will be performed only on annual leave time or during leave without pay.

2. The Consultant will not disclose to the I.O. any information derived from work performed at the NIH until it has been disclosed publicly, either in a written publication, or presented orally at a meeting open to the public and publicly announced.

3. Consultation will relate only to the general knowledge and expertise of the Consultant, and may be performed on an ongoing basis for the I.O., however all information concerning NIH research shall be provided on a non-exclusive basis. Any and all agreements for exclusive consultation are prohibited.

4. The I.O. will have no proprietary interest in any work that the employee has done or will do at the NIH.

5. It is understood by the parties that the substance of the consulting agreement is independent of that of any collaborative agreements. Services to be rendered by the employee in the consulting agreement are independent and unrelated to those performed under official duties involving collaborative agreements.

6. Notwithstanding any other provision in this Agreement, the Consultant must report any invention made by the Consultant (whether alone or jointly) to the Department of Health and Human Services (DHHS) as required by Federal regulations in 45 CFR Part 7,* nor shall DHHS be restricted or precluded by anything in this agreement from ascertaining its rights in such an invention.

*These regulations require the reporting of any invention made by a DHHS employee that bears any relation to his/her official duties, or that was made in whole or in part during working hours, or with any contribution of Government facilities, equipment, material, funds, or information or of time or services of other Government employees on official duty.

7. Except to the extent it may interfere with the obligation in item 6 above, the Consultant agrees not to divulge to other parties confidential or proprietary information provided by the I.O.

8. The I.O. will not refer to the Consultant or to an affiliation with NIH in anything distributed for publicity or product promotion.

9. The number of days the Consultant will work for the I.O. during calendar year 1985 are to be: _____; and during 1986 are to be: _____.

10. The method and amount of compensation for the Employee's services and expenses will be as follows:

11. This Consulting Agreement shall become effective the date of NIH approval of the Consultant's participation in this Outside Activity.

==========

ACCEPTED AND AGREED TO FOR THE INDUSTRIAL ORGANIZATION:

Signature of Designated Official: _____

Typed Name: _____ DATE: _____

Position in Organization: _____

Address: _____

_____ PHONE: _____

ACCEPTED AND AGREED TO BY THE NCI EMPLOYEE/CONSULTANT:

I will observe the policies and regulations which govern outside activities as defined in the NIH Manual 2300-735-4 (8/1/85) and the DHHS Standards of Conduct.

Signature of Employee: _____

Typed Name: _____ DATE: _____

Title of Position: _____

Location & Phone: _____

This completed Agreement is to be submitted together with Form HHS-520, "Request For Approval Of Outside Activity," for all consultative services for outside organizations, as defined by the NIH regulations. Completed forms should be submitted to the employee's supervisor at least 6 weeks in advance of the requested activity to permit appropriate processing and approval prior to initiation.

☐ NIH Approval Granted: _____ (Date) ☐ NIH Approval Denied: _____ (Date)

#8B

CHECKLIST FOR CONSULTING AND LECTURING FOR INDUSTRY

Instructions: This checklist is for applicants seeking approval to engage in consultation for industry as an outside activity, and for the reviewers of such requests. There are questions for both the initiator and the reviewing Lab/Branch Chief. Check YES or NO after each question.

*If the answer to any question is YES, attach a separate sheet providing additional information on the item.

A completed checklist, plus a signed Consulting Agreement, must accompany each Form HHS-520 which requests approval for industrial consulting. The three documents should be submitted to the Division Director for review at least six weeks prior to any proposed consultation.

	YES*	NO
A. APPLICANT'S CHECKLIST		
1. Have you ever requested and been denied approval for this outside activity before?	____	____
2. If the proposed outside activity is to be a lecture for industry, will the fee to be received from the lecture (excluding any amount paid for travel and subsistence expenses) exceed $2,000?	____	____
3. Will the fee/honorarium to be received for the proposed industrial lecturing/consultative service(s) exceed $12,500 (excluding any amount paid for travel and subsistence expenses) either in this instance or in the aggregate from this industrial employer this calendar year?	____	____
4. Will the fee to be received for the proposed industrial consulting or lecturing cause your outside income from all industrial sources to exceed a total of $25,000 for either consulting or lecturing this calendar year?	____	____
5. Do you or any member of your family own stock, have stock options or any other financial interest in the industrial organization for which you propose to work?	____	____
6. Are there any conditions or circumstances which would prevent you from complying with any of the terms of the standard NCI Consulting Agreement with an industrial organization?	____	____
7. As a part of your official responsibilities, have you made procurement or financial decisions, or are there any pending decisions that you will have to make, which will affect the business prospects of your proposed employer?	____	____

4.04 — representatives to the Research Committee shall, prior to the execution of any and all RPA's and periodically thereafter, review with the — Principal Investigator(s) the prior, current, and proposed assignments of — Personnel performing research under this Agreement to determine whether — Personnel have in the past, or are currently performing, or propose to perform, related research under any other agreement between — and a third party. — representatives shall discuss their findings with Co. representatives and, if in the opinion of Co. representatives further investigation is warranted, — Patent Counsel will, at the request of the Research Committee, use reasonable efforts to review the situation to determine whether any actual or potential conflict exists between the obligations undertaken or proposed to be undertaken by — hereunder with respect to patentable inventions and biological materials, and those obligations undertaken by MIT in such other agreement(s). If a potential conflict does exist, — Patent Counsel will so report to the Research Committee which will (upon request by Co. representatives) request such — personnel to elect which of the potentially conflicting projects they choose to participate in. If — Patent Counsel believes that the investigation of conflicts cannot reasonably be completed he will so inform the Research Committee along with the reasons for his conclusion and the parties shall then discuss an appropriate resolution of the situation.

2. Other Agreements. It is recognized that the work of some proposed project participants may be supported in whole or part under contracts and grants between the University and other parties. Prior to the participation of such an individual or the use of equipment owned by other sponsors in a joint study project, ——— will use its best efforts to identify and disclose to Co. any terms in those contracts which may conflict with ——— obligations under this Agreement. Co. may, at its option, and in writing, agree to waive or alter any such conflicting rights under this Agreement in favor of those prior obligations so disclosed. If Co. does not agree to waive or alter any such conflicting right in a manner satisfactory to ——— the individual will not be able to participate in that portion of the work under this Agreement as to which such conflict arises. Co. understands some ——— employees have private consulting agreements with third parties, to which the University is not privy and for which it disclaims all responsibility.

Section 11. Government Obligations

Nothing in this Agreement shall be construed to restrict the right of MIT to transfer to the United States Government such rights as the Government may be entitled to under any agreement MIT may have or may hereafter enter with the Government, whether or not consistent with the provisions of this Agreement.

24. Independent Inquiry. Nothing in this Agreement shall be construed to limit the freedom of researchers who are not participants in this Agreement, whether paid under this Agreement or not, from engaging in similar research inquiries made independently under other grants, contracts or agreements with parties other than Sponsor.

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D.1.1. PERIOD OF PERFORMANCE. The research shall be conducted during the period _____ through _____ and will be subject to renewal only by mutual agreement of the parties.

4. Period of Performance. This Agreement is effective for the period *[DATE] through *[DATE] and may be extended only by written agreement of the parties.

ARTICLE III - TERM

3.1 This Agreement shall be for a period of three (3) years commencing July 1, 1981.

3.2 On or about the conclusion of the second year of this Agreement the parties shall enter into discussions as to whether both parties desire to continue the Program beyond the termination date of this Agreement. If continuation is mutually desirable the parties shall proceed with negotiations to arrive at mutually acceptable terms and conditions for such continuation.

3.3 If, in accordance with paragraph 3.2 the parties decide not to continue the Program beyond the stated term of this Agreement, then the Company shall have the option of continuing its support, on a Project by Project basis, for any Project started but not completed during the stated term. The Company shall make such elections and the parties shall negotiate in good faith mutually acceptable time extension and financial terms prior to the expiration of this Agreement. All other relevant terms of this Agreement shall apply to such terminal project continuations.

12. Termination. This Agreement may be terminated by either party at any time upon the receipt of 60 days written notice to the other party. Upon notification, ——— shall proceed in an orderly fashion to limit or terminate any outstanding commitments and to conclude the work. All costs associated with termination shall be allowable including, without limitation, all costs or noncancellable commitments incurred prior to the receipt of the notice of termination which have not been reimbursed to ——— If any ——— student is supported under this Agreement, Sponsor shall remain liable for the full costs of such student support through the end of the academic quarter in which this Agreement terminates. In the event of termination, ——— shall submit a final report within 120 days of the effective date of termination of all costs and commitments incurred and all funds received. The report shall be accompanied by a check in the amount, if any, of the excess of funds advanced over costs and allowable commitments incurred, or if appropriate, by an invoice for costs and commitments incurred in excess of funds provided due and payable within 30 days.

D.2.1. TERMINATION. Performance under this agreement may be terminated by the Sponsor upon sixty days written notice; performance may be terminated by the Institute if circumstances beyond its control preclude continuation of the research. Upon termination, the Institute will be reimbursed as specified in Article ___ for all costs and non-cancellable commitments incurred in the performance of the research, such reimbursement not to exceed the total estimated project cost specified in Article ___.

D.2.2. TERMINATION. This Agreement may be terminated by either party at any time upon giving the other party sixty (60) days prior written notice to the other party. Upon the giving of notice of termination, both parties shall procedd in an orderly fashion to terminate any outstanding commitments and to conclude the work. All costs associated with termination shall be allowable, including without limitation, costs and noncancellable commitments incurred prior to the notice of termination which have not been reimbursed to the Institute. In the event of termination, the Institue shall prepare a final report within ninety (90) days of the effective date of termination of all costs incurred and all funds received. The Institute shall send one (1) copy of the report to the Sponsor and shall accompany such report with a check in the amount, if any, of the excess of funds acvanced over costs incurred. If any costs are due to the Institute, such costs shall be paid to it forthwith.

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E. COSTS AND PAYMENT

E.1.1. REIMBURSEMENT OF COSTS. In consideration of the foregoing, the Sponsor will reimburse the Institue for all direct and indirect costs incurred in the performance of the research which shall not exceed the total estimated project cost of _____ without written authorization from the Sponsor.

E.1.2. REIMBURSEMENT OF COSTS (additional). The estimated direct cost of the Institute's research projects consists of the salaries and wages of project personnel, including associated employee benefits, and equipment, materials and services, travel and any other direct costs necessary for performance of the project.

In addition to the foregoing direct costs, the project costs include an allocable share of the Institute's indirect costs. Institute indirect costs cover maintenance of the physical plant and facilities, the libraries, the general and administrative services and other Institute support services.

E.2.1. BUDGET FLEXIBILITY. In performing the research, the Institute agrees not to exceed the total estimated cost unless it is increased by written authorization from the Sponsor. However, within that total cost, the costs accumulated under each of the various budget categories may change in order to adapt to the needs of the project as the research progresses. To maintain the needed flexibility, the Institute must reserve the right to shift funds between budget categories at the discretion of the principal investigator.

E.3.1. PAYMENT Payments shall be made to the Institute by the Sponsor in advance on the following basis or schedule:

_____

E.4.1. FISCAL REPORTS. A final financial accounting of all costs incurred and all funds received by the Institute hereunder together with a check for the amount of the unexpended balance, if any, shall be submitted to the Sponsor within ninety days following the completion of the project.

E.5.2. FINANCIAL RECORDS. The Institute will maintain records of its costs hereunder and of funds received in accordance with its regular policies and procedures based on recognized institutional accounting principles consistently applied. The Sponsor shall have the right to examine the Institute's accounting records relating to this Agreement, on reasonable advance written notice, at the Institute during the term of this Agreement and for a period of one (1) year following the expiration of this Agreement.

5. Reimbursement of Costs. (a) _____ shall be reimbursed for all costs incurred by it in connection with the Research up to the amount of $*[AMOUNT SPELLED OUT] (the "Research Cost"). It is estimated that the amount designated as the Research Cost is sufficient to support the costs of the Research, but _____ may submit to Sponsor a revised budget requesting additional funds at such time as costs may reasonably be expected to exceed the Research Cost. Sponsor shall not be liable for any payment in excess of the Research Cost unless this Agreement is modified in writing.

(b) Within 120 days of the termination of this Agreement, _____ shall submit a final financial report setting forth costs and commitments incurred and funds received. The report shall be accompanied by a check in the amount, if any, of the excess of funds advanced over costs and commitments incurred.

6. Payment. (a) Sponsor shall make payments to _____ according to the following schedule:

1. Within ten days of execution of this Agreement $*
2. *[SPECIFIED DATE] $*
3. *[SPECIFIED DATE] $*
4. *[CONTINUE AS NEEDED] $*

(b) Checks shall be made payable to _____ and shall be sent to:

_____
_____
_____
_____
_____

(c) Each payment shall include the title of the Research and the name of the Principal Investigator, for purposes of identification.

15. Indemnification. Sponsor hereby waives and agrees to indemnify, defend, and hold harmless ——— from any loss, claim, damage, or liability of any kind involving an employee of Sponsor arising out of or in connection with this Agreement, except to the extent that such loss, claim, damage, or liability arises in whole or in part from the negligence of Stanford.

16. WARRANTIES. ——— MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AS TO ANY MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, THE CONDITION OF THE RESEARCH OR ANY INVENTION(S) OR PRODUCT(S), WHETHER TANGIBLE OR INTANGIBLE, CONCEIVED, DISCOVERED, OR DEVELOPED UNDER THIS AGREEMENT; OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR ANY SUCH INVENTION OR PRODUCT. ——— SHALL NOT BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL, OR OTHER DAMAGES SUFFERED BY ANY LICENSEE OR ANY OTHERS RESULTING FROM THE USE OF THE RESEARCH OR ANY SUCH INVENTION OR PRODUCT.

ARTICLE X - INDEMNIFICATION

10.1 The Company agrees to hold harmless, indemnify and defend the University from all liabilities, demands, damages, expenses and losses arising out of use by the Company, or by any party acting on behalf of or under authorization from the Company, of University Technical Developme or out of any use, sale or other disposition by the Company, or by any party acting on behalf of or under authorization from the Company, of products made by use of University Technical Developments. The provisions of this paragraph shall survive termination of this Agreement.

G. USE OF THE INSTITUTE/SPONSOR NAME

G.1.1. USE OF INSTITUTE/SPONSOR NAME. Neither party will use the name of the other in any form of publicity without the written permission of the other; in the case of the Institute, that of the Director of the News Office.

14. Publicity. Neither party shall use the name of the other in connection with any products, promotion, or advertising without the prior written permission of the other party.

16.1 Except as provided in Paragraph 9.5, neither party shall use the name of the other party, its affiliated organizations or its personnel in advertising or promotional materials or news or press releases pertaining to the subject matter of this Agreement without prior written consent of such other party.

ARTICLE XIII - ASSIGNMENT - PARTIES BOUND

13.01 This Agreement shall be binding upon and inure to the benefit of the parties hereto and the successors to those portions of the business and/or assets of the respective parties hereto to which this Agreement pertains. This Agreement shall not be assignable by either party hereto without the prior written consent of the other party. Any and all assignments of this Agreement or of any interests therein not made in accordance with this Paragraph 13.01 shall be void. Any licenses granted by — to Co. pursuant to this Agreement shall be assignable only with prior consent of — which consent shall not be unreasonably withheld.

20. Assignment. Neither party shall assign this Agreement to another without the prior written consent of the other party; provided, however, that Sponsor may assign this Agreement to a successor in ownership of all or substantially all its business assets. Such successor shall expressly assume in writing the obligation to perform in accordance with the terms and conditions of this Agreement. Any other purported assignment shall be void.

ARTICLE XI - TRANSFER OF INTEREST

11.1 Neither this Agreement, nor any of its rights and obligations, may be assigned, transferred or otherwise disposed of by either party without the prior written consent of the other unless such assignment, transfer or disposition is to a successor to all the business and assets of the transferor which pertain to the subject matter of this Agreement, and provided that such successor shall agree in writing with the other party to assume all the obligations of the transferor under this Agreement in a form satisfactory to the other party.

ARTICLE XII - ADDRESSES AND NOTICES

12.01 The addresses of the parties hereto are as follows, but either party may change its address for the purpose of this Agreement by notice in writing to the other party:

12.02 All notices, payments, statements and reports required or permitted to be given under this Agreement shall be sent to the addresses set forth in Paragraph 12.01. When any of said notices, payments, statements or reports are sent by certified or registered mail to the other party entitled thereto at its address as set forth above, they shall be deemed to have been given or made as of the date so mailed.

ARTICLE XV - NOTICE

15.1 Any notice or report required or permitted to be given under provisions of this Agreement shall be in writing and be sent by first class mail or hand delivered:

13. Notices. Any notices given under this Agreement shall be in writing and delivered by first-class mail, postage prepaid, or by telex addressed to the parties as follows:

ARTICLE XV - FORCE MAJEURE

15.01 Neither party hereto shall be responsible to the other for failure to perform any of the obligations imposed by this Agreement, provided such failure shall be occasioned by fire, flood, explosion, lightning, windstorm, earthquake, subsidence of soil, failure or destruction, in whole or in part, of machinery or equipment or failure of supply of materials, discontinuity in the supply of power, governmental interference, civil commotion, riot, war, strikes, labor disturbance, transportation difficulties, labor shortage or any cause beyond the reasonable control of the party in question.

17. Force Majeure. [redacted] shall not be liable for any failure to perform as required by this Agreement, to the extent such failure to perform is caused by any reason beyond [redacted] control, or by reason of any of the following occurrences: labor disturbances or labor disputes of any kind, accidents, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, floods, earthquakes, acts of God, energy or other conservation measures, explosion, failure of utilities, mechanical breakdowns, material shortages, disease, or other such occurrences.

ARTICLE XVI - DISPUTES

16.01 The parties hereto recognize that it would be in their mutual interest to resolve all disputes on an amicable basis. Accordingly, the parties shall exercise all reasonable efforts to resolve such disputes by: (i) the Research Committee or, concerning anticipated licensing agreements, by negotiations between appropriate personnel from MIT and and, if not resolvable on that basis; by (ii) a management committee consisting of two members, one appointed by each party. The initial appointees to the management committee shall be Kenneth A. Smith for MIT and for

19. Arbitration. Any dispute arising between the parties in connection with this Agreement which cannot be resolved by mutual agreement shall be finally settled under the Rules of Conciliation and Arbitration of the American Arbitration Association by one or more arbitrators appointed in accordance with the Rules. Any such arbitration shall be held in or at such other location as the parties may agree.

23. Entire Agreement; Changes. This Agreement and its Appendices contain the entire agreement between the parties. No amendments or changes to this Agreement shall be effective unless made in writing and signed by authorized representatives of and Sponsor. All correspondence regarding terms of this Agreement shall be sent as specified in the Paragraph entitled Notices.

13.5 This writing constitutes the entire Agreement between the parties hereto relating to the subject matter of this Agreement and there are no understandings, representations or warranties of any kind except as expressly provided herein. Neither this Agreement, nor any term or provision thereof, may be discharged, waived, released, abandoned, changed or modified except by an instrument in writing signed by a duly authorized representative of each of the parties to this Agreement. If either party desires a modification or change of any kind in this Agreement, the parties shall, upon reasonable notice of the proposed modification or change by the party desiring the change, confer in good faith to determine the desirability of such modification or change.

16.6 The parties agree that it is the intention of neither party to violate any valid federal, state and local laws and regulations; that if any sentence, paragraph, clause, or combination of the same in this Agreement is in violation of any applicable law or regulation, or is unenforceable or void for any reason whatsoever, such sentence, paragraph, clause or combinations of the same shall be inoperative and the remainder of the Agreement shall remain binding upon the parties.

13.3 No waiver of any default, condition, provisions or breach of this Agreement shall be deemed to imply or constitute a waiver of any other like default, condition, provision or breach of this Agreement.

13.4 The Article headings used in this Agreement are for convenience only and form no part of the Agreement.

21. Severability. In the event a court of competent jurisdiction holds any provision of this Agreement to be invalid, such holding shall have no effect on the remaining provisions of this Agreement, and they shall continue in full force and effect.

17.04 No amendment, change or modification of this Agreement shall be effective unless in writing signed by each of the parties hereto.

A. RECITALS

A.1.1. RESEARCH AGREEMENT between the MASSACHUSETTS INSTITUTE OF TECHNOLOGY, hereinafter referred to as "the Institute", and _____ hereinafter referred to as "the Sponsor".

A.2.1. WHEREAS, the research program contemplated by this agreement is of mutual interest and benefit to the Institute and to the Sponsor, and will further the instructional and research objectives of the Institute in a manner consistent with its status as a non-profit, tax-exempt, educational institution,

NOW, THEREFORE, the parties hereto agree as follows:

A.2.2. WHEREAS, the Institute and the Member have a mutual interest in the advancement of technology in the field of _____ and wish to interact in a program of research ranging from fundamental to concentrated or focused research in this field,

WHEREAS, the Institute and the Member view such interactions as conducive to the ultimate aims of technology transfer,

WHEREAS, the program contemplated by this agreement will further the instructional and research objectives of the Institute in a manner consistent with its status as a non-profit, tax-exempt, educational institution,

NOW, THEREFORE, the parties hereto agree as follows:

3. Independent Contractor. _____ is an independent contractor and not an agent, joint venturer, or partner of Sponsor.

C.1.1. INDEPENDENT CONTRACTOR. The Institute's relationship to the Sponsor under this agreement shall be that of an independent contractor. The Institute shall have complete and sole control and responsibility over the research performed under this agreement and the Institute's personnel.

C.2.1. PRINCIPAL INVESTIGATOR. The research will be supervised by _____ If, for any reason, (s)he is unable to continue to serve as Principal Investigator, and a successor acceptable to both the Institute and the Sponsor is not available, this agreement shall be terminated as provided in Article _____.

2. Key Personnel. (a) The following individuals are identified as key personnel for the performance of the Research:

1.*[NAME], Principal Investigator

2.*[NAME], (Other)

3.*[NAME], (Other)

(b) If for any reason *[NAME] withdraws from serving as Principal Investigator, _____ and Sponsor shall endeavor to agree upon a successor. If the parties are unable to agree upon a successor, this Agreement shall be terminated in the manner provided in the paragraph entitled Termination.

B.4.1. BEST EFFORTS. The Institute agrees to use its best efforts (1) to accomplish the research or studies described in the statement of work and (2) to do so within the total estimated cost and within the stated period of performance. It is understood, however, that if funds are exhausted before the project is completed, the principal investigator will, at the option of the sponsor, etiher submit a report on what has been accomplished to date, or will provide an estimate of further funds required to complete the work and will continue if such funds are provided by the Sponsor."

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ARTICLE II - PROJECTS AND RESEARCH COMMITTEE

2.01 CO. and — shall each appoint four (4) representatives and such representatives shall then collectively constitute the Research Committee. Each party hereto shall have the right, in its sole discretion, to appoint substitute representatives upon prior written notice to the other party.

2.02 The Research Committee shall invite proposals from interested — faculty within the Field of this Agreement. After the normal proposal review at — the Research Committee shall select the proposals considered most appropriate for funding pursuant to this Agreement. The Principal Investigator(s) for a selected proposal shall then prepare a Request for Project Authorization ("RPA"). Each RPA shall set forth sufficient information so that both parties can fully understand the research to be performed including the objectives thereof, work tasks, period of performance, annual budget, Principal Investigator(s), other — Personnel to be involved, the minimum percentage of individual research time that each of the — Principal Investigator(s) shall devote to the research project, and the disposition of rights in intellectual property.

2.03 The Research Committee shall review the RPA's and those that are approved for funding shall be submitted to the authorized representatives of the parties (as designated in writing by each party to the other from time to time) for approval. Written approval of any given RPA by the authorized representatives of both parties shall constitute authorization for ___ to proceed with performance of the Project. A copy of each fully approved RPA shall be annexed to and become a part of this Agreement. In the event of an inconsistency between the RPA and this Agreement, the terms of the RPA shall prevail.

2.04 ___ shall make no changes in: (a) the designation of the Principal Investigator(s); or (b) the minimum amount of research time to be devoted by each Principal Investigator in performing a Project without the express written unanimous concurrence of the Research Committee.

2.05 The Research Committee shall establish its own procedures and shall be responsible for providing guidance and administration for all Projects. As part of its overall responsibilities the Research Committee shall:

(i) periodically review each Project's objectives, the results and data generated

under each Project, work tasks, annual budget, period of performance, assignment of ___ Personnel and any other matters relating to the Project and shall propose such changes therein as it deems appropriate; and

(ii) make recommendations to the parties for the preparation and filing of Contract Patent Rights, — / Co. Patent Rights, and Genetic Copyrights.

2.06 All decisions by the Research Committee to make changes in a Project (pursuant to Paragraph 2.05(i) hereinabove) shall be: (i) made by unanimous vote; (ii) reflected in written document(s) signed by all members of the Research Committee; and (iii) concurred in by the Principal Investigator(s) if he/she or they are not already members of the Research Committee. Copies of such document(s) shall promptly thereafter be transmitted to — and Co. When countersigned by Co. and — each RPA affected thereby shall be deemed to be amended to the extent, and as of the date reflected in such document(s).

2.07 Within the funding limits provided under Paragraph 3.02, — shall be entitled to carry on one or more Discretionary Research Projects. Funding for the Discretionary Research Projects shall be provided by Co. pursuant to Paragraphs 3.02 and 10.01. The amount of funds allocated to each Discretionary Research Project shall be determined by the — representatives to the Research Committee.

B.2.1. STATEMENT OF WORK. The Institute agrees to use its best efforts to perform the research program entitled _____ as described in _____.

1. Statement of Work. _____ agrees to use reasonable efforts to perform the research program described in Exhibit A (the "Research"), which Exhibit is hereby incorporated herein. Sponsor acknowledges that _____ expressly makes no warranties nor representations with respect to its ability to accomplish the Research.

B.2.2. ANNUAL REPORTS. The Institute shall furnish the Sponsor annual written reports during the term of this agreement summarizing the research conducted during the previous period. A final report setting forth the accomplishments and significant research findings shall be prepared by the Institute and submitted to the Sponsor within ninety days after completion of the project.

10. Reports. _____ shall furnish Sponsor letter reports during the term of this Agreement summarizing the research conducted. A final report setting forth the accomplishments and significant research findings shall be prepared by _____ and submitted to Sponsor within 90 days of the expiration of the Agreement.

ARTICLE VI

INTERACTION BETWEEN ——— AND THE UNIVERSITY

6.1 To optimize the mutual benefit and collaboration intended by this Program, the parties desire that there be mutually productive and continuing interchanges between University and Co. scientists. Accordingly, the University will ensure that all University scientists engaged in the Program are available to appropriate Co. scientists for consultation in the area of their respective Projects. Temporary office space at the University shall be made available to collaborating Co. scientists.

6.2 The University agrees to permit individual scientists and technicians from Co., with the consent of the Program Director and Project Investigator and at Co's. expense, to spend appropriate periods of time in University laboratories where Project research is being conducted to learn techniques developed therein, to participate if mutually desirable, and to facilitate the transfer of Technical Developments to Co. Co. agrees that its employees who are permitted to train and function in the laboratories of the University pursuant to this paragraph shall be required to observe the applicable policies of the University.