FACULTY STATEMENT OF

PRINCIPLES & BEST PRACTICES CONCERNING STRATEGIC CORPORATE ALLIANCES Spring 2005

This document has four parts:

HISTORY, SCOPE & APPLICATION – describes the process by which the Statement was created and adopted, its relationship to relevant Administration and Trustee documents, and its intended scope and function. The definition of "strategic corporate alliance" – which is a University definition – appears here.

GENERAL OBSERVATIONS – compares and contrasts the typical mission of the for-profit corporation and the research university, notes Cornell's distinctive history of commitment to *both* academic independence and openness *and* practical collaboration, and describes faculty ambivalence about the possible benefits and risks of SCAs. The importance of ongoing monitoring and rigorous subsequent evaluation is emphasized here.

STATEMENT OF PRINCIPLES AND BEST PRACTICES – provides a set of overarching normative propositions, particularized by more specific directives and explanatory text, to be applied during the targeting, negotiation, approval, implementation, and oversight of strategic corporate alliances.

APPENDICES A-D – contain relevant Administration and Trustee documents and a bibliography.

The TABLE OF CONTENTS serves as a substantive outline of the Statement, as well as a locator. The INDEX not only helps find specific issues and terms but also provides a summary of some important concepts.

Respectfully submitted,

Elizabeth D. Earle, Plant Breeding & Genetics

John M. Guckenheimer, Mathematics (joining in this Statement except for Section D)

Anthony R. Ingraffea, Civil & Environmental Engineering

David A. Levitsky, Nutritional Science

Risa L. Lieberwitz, Industrial and Labor Relations

David L. Pelletier. Nutritional Science

Peter C. Stein, Physics

Steven A. Wolf, Natural Resources

Elaine Wethington, Human Development

Cynthia R. Farina, Associate Dean of the Faculty, Chair (non voting)

Charles Walcott, Dean of the Faculty, ex officio

TABLE OF CONTENTS

HIS	TORY	, SCOPE AND APPLICATION	.5	
		AT ARE STRATEGIC CORPORATE ALLIANCES, AND WHAT IS THEIR ORIGIN AT	. 5	
	WHA	AT OTHER ADMINISTRATION AND TRUSTEE DOCUMENTS DIRECTLY ADDRESS SCAS	. 6	
		AT PROCESS PRODUCED THE FACULTY STATEMENT OF PRINCIPLES AND TPRACTICES?	. 6	
		V DOES THIS STATEMENT ALIGN WITH THE RELEVANT ADMINISTRATION AND STEE DOCUMENTS?	. 7	
	WHA	AT IS THE FUNCTION OF THIS STATEMENT?	. 7	
		AT IS THE INTENDED RELATIONSHIP BETWEEN THE GENERAL PRINCIPLES AND ACCOMPANYING TEXT?	. 8	
	To V	What Sort of Sponsorship Arrangements Does This Statement Apply?	. 8	
		AT SORT OF SPONSORSHIP ARRANGEMENTS ARE NOT INTENDED TO BE GOVERNED THIS STATEMENT?	. 8	
	WHY	Y Distinguish Between SCAs and Other Forms of Sponsored Research?	.9	
GEI	NERAL	_ OBSERVATIONS1	10	
PRI	NCIPL	ES & BEST PRACTICES	11	
A.	TO	THE POWER TO CHOOSE RESEARCH TOPICS FREELY AND THE ABILITY TO PUBLISH RESULTS PROMPTLY, WITHOUT REGARD TO OUTCOME, ARE BASIC ELEMENTS OF ACADEMIC FREEDOM		
	1.	RESEARCH AUTONOMY SHOULD BE SAFEGUARDED	11	
	2.	RESTRICTIONS ON RELATIONSHIPS BETWEEN FACULTY OR STUDENTS AND "COMPETITORS" OF THE CORPORATE PARTNER SHOULD BE MINIMIZED	13	
	3.	INTERFERENCE WITH PUBLICATION (INCLUDING DELAY FOR FIRST-LOOK REVIEW) SHOULD BE MINIMIZED	14	

	4.	LICENSING OF INVENTIONS DERIVED FROM SCA-FUNDED WORK SHOULD ALWAYS RESERVE ACADEMIC USE & DISTRIBUTION RIGHTS, AND SHOULD
		BE Non-Exclusive to the Extent Reasonably Possible
	5.	Any Interference With Academic Freedom Should Be Reported to the Dean of the Faculty, Who in Addition to Counseling Ordinary Remedies Will Ensure That Such Reports Are Tracked
В.	PRE HAV	DEMIC FREEDOM ENTAILS THE RESPONSIBILITY TO UNDERTAKE AND SENT RESEARCH WITH OPENNESS AND INTEGRITY, AND CONDITIONS OF TO BE MAINTAINED IN WHICH FACULTY CAN FULFILL THIS PONSIBILITY
	1.	No Restrictions on Revealing The Sponsorship Relationship Are Permissible
	2.	MULTIPLE SIMULTANEOUS RELATIONSHIPS WITH THE CORPORATE PARTNER SHOULD BE CAREFULLY MANAGED
	3.	Any Interference with a Faculty Member's Responsibility To Publish Results, Regardless of Effect on the Sponsor, Is Unacceptable 18
C.		ISIONMAKING AUTHORITY OVER CORNELL RESEARCH HAS TO REMAIN MARILY WITH CORNELL DECISIONMAKERS19
	1.	THE MANAGEMENT GROUP SHOULD CONTAIN NON-PARTICIPATING, AS WELL AS PARTICIPATING, FACULTY
	2.	DAY-TO-DAY MANAGEMENT OF THE SCA SHOULD BE PREDOMINANTLY BY CORNELL FACULTY, NOT CORPORATE REPRESENTATIVES
	3.	SELECTION OF FACULTY PROPOSAL FOR FUNDING SHOULD NOTE BE DICTATED BY CORPORATE REPRESENTATIVES
D.	PEE: NEE	HE CASE OF CERTAIN SCAs ("BROAD SCAs"), OBJECTIVE STANDARDS, R REVIEW, AND SOME FORM OF EXTERNAL ACCOUNTABILITY ARE DED TO PROTECT ACADEMIC INTEGRITY IN THE FUNDING PROCESS TO ENHANCE FAIRNESS
	1.	THE JOINT STEERING COMMITTEE SHOULD PREPARE REQUESTS FOR PROPOSALS THAT SPECIFY AS CLEARLY AS POSSIBLE THE CRITERIA THAT WILL GOVERN GRANT AWARDS AND THE PROCESS FOR APPLICATION
	2.	PROPOSALS SHOULD BE EVALUATED BY NON-PARTICIPATING CORNELL FACULTY COMPETENT TO ASSESS THEIR MERIT 21

	3.	ACCOUNTABI	CISIONS SHOULD BE MADE IN A WAY THAT ENHANCES LITY, BE THE SUBJECT OF PERIODIC EXTERNAL REPORTING21	
E.	THE FACULTY, THROUGH ITS REPRESENTATIVES, SHOULD HAVE A CENTRAL ROLE IN THE APPROVAL AND OVERSIGHT OF SCAS22			
	1.	SHOULD BE IN IS NOT A FAIT LAC APPROV	ULD BE ENTERED INTO WITHOUT THE APPROVAL OF LAC, WHO NVOLVED EARLY ENOUGH IN THE PROCESS THAT THE AGREEMENT ACCOMPLI. AMENDMENTS TO AN SCA SHOULD ALSO RECEIVE TAL. LAC SHOULD REPORT ITS CONCLUSIONS TO THE DEAN OF THE WELL AS TO THE APPROPRIATE ADMINISTRATION OFFICIALS 22	
	2.	RECEIVING FR AND OTHER IN ITS CONCLUSI	REVIEW THE PERFORMANCE OF EVERY ONGOING SCA ANNUALLY, AND THE JSC AND/OR THE ALLIANCE DIRECTOR PERIODIC REPORTS NOT AS NEEDED TO PERFORM THIS REVIEW. LAC SHOULD REPORT HONS TO THE DEAN OF THE FACULTY, AS WELL AS TO THE APPROPRIATE TION OFFICIALS	
	3.	AND REVIEWE	ADEQUATELY THE FUNCTIONS OF APPROVING SCA AGREEMENTS NG THEIR IMPLEMENTATION, THE COMPOSITION OF LAC SHOULD ED	
	4.		TO EVALUATIONS OF EACH SPECIFIC SCA, BROADER STUDIES OF THE ENCE AT CORNELL SHOULD BE UNDERTAKEN	
F.	CORP	ORATE PART	S BEEN FINALLY APPROVED BY CORNELL AND THE INER, THE TERMS OF THE SCA SHOULD BE MADE HE CORNELL COMMUNITY	
INDE	X	•••••	27	
APPENDICES APPENDIX A			Cornell University Strategic Corporate Alliance Plan (7/30/03)	
	APPENDIX B APPENDIX C		TRUSTEE DOCUMENT: CONSIDERATIONS & PRINCIPLES REGARDING STRATEGIC CORPORATE ALLIANCES (MAY 22, 2003)	
			CURRENT CORNELL PRINCIPLES TO GUIDE DEVELOPMENT OF STRATEGIC CORPORATE ALLIANCES (UNDATED)	
	APPE	NDIX D	BIBLIOGRAPHY	

HISTORY, SCOPE AND APPLICATION

What Are Strategic Corporate Alliances, and What Is Their Origin at Cornell?

On July 30, 2003, the Administration completed the Cornell University Strategic Corporate Alliance Plan ("the Plan"), the objective of which is "[t]o leverage access to Cornell University intellectual capital, including faculty research, into major corporate alliances leading to competitive opportunities for select companies and financial support for faculty research and related infrastructure."

The Plan defines a Strategic Corporate Alliance ("SCA") as

a comprehensive, formally managed company-university agreement centered around a major, multi-year financial commitment involving research, programmatic interactions, intellectual property licensing, and other services.²

The initial target industries are affiliated with the New Life Sciences Initiative, but the Plan contemplates "expand[ing] the alliance concept to other industries beyond the scope of the New Life Sciences."

At a University Faculty Forum held on October 22, 2003, Vice President Inge Reichenbach explained the process that led to the Plan⁴: The Plan was the project of the Division of Alumni Affairs & Development, the Vice Provost for Research, and the Vice Provost for the New Life Sciences, in consultation with the Research Subcommittee of the Board of Trustees. That subcommittee spent six meetings discussing the SCA initiative. Also involved were the Office of Sponsored Programs and an informal New Life Sciences advisory council group. Special meetings were held with the Life Sciences and Food Sciences faculty, as well as two general meetings open to all faculty. Additionally, Vice President Reichenbach explained, the Trustees visited two institutions with SCA experience: MIT, which has been doing SCAs since the 1950s and which currently gets 45% of its corporate research sponsorship in this form; and Partners Health Care System, the teaching hospital related to Brigham and Women's and Massachusetts General Hospital, whose faculty is affiliated with Harvard Medical School. The earlier draft of the Plan was discussed with the University Faculty Committee ("UFC")⁵ and reviewed by the Local Advisory Council ("LAC").⁶

¹ Cornell Strategic Alliance Plan (7/30 version) at 1 [Appendix A]. This version of the Plan superseded an earlier draft.

² Id.

³ Id. at 1,4.

⁴ Vice President Reichenbach's remarks, and the transcript of the rest of the Faculty Forum, can be found at http://web.cornell.edu/UniversityFaculty/.

⁵ The UFC advises the Dean of the Faculty and serves some of the functions of an executive committee of the Faculty Senate.

What Other Administration and Trustee Documents Directly Address SCAs?

In addition to the Strategic Corporate Alliance Plan (7/30/03), which is attached as Appendix A, the process described above produced two other documents intended to govern SCAs:

- Trustee Document: Considerations & Principles Regarding Strategic Corporate Alliances (May 22, 2003), issued by the Research Subcommittee of the Board of Trustees, attached as Appendix B
- Cornell Document: Current Cornell Principles to Guide Development of Strategic Corporate Alliances (undated), attached as Appendix C

These three documents are essential background for this Statement. Faculty unfamiliar with them may wish to review them before reading the Statement.

What Process Produced The Faculty Statement of Principles and Best Practices?

As a result of the October 2003 University Faculty Forum, the Dean of Faculty and the UFC determined it would be appropriate for the Faculty to do as the Administration and the Trustees have already done:

- thoughtfully consider the implications of a commitment by Cornell to pursue corporate research support in the particular form of strategic corporate alliances (as that concept is defined in the Plan); and
- attempt to formulate a set of principles and practices that should govern Cornell's actions in such alliances.

As paragraph V of the Trustee Document appropriately recognizes:

Faculty should be deeply involved in the planning, execution, and monitoring of any plan for a specific strategic alliance, as well as being involved in and committed to the creation of the plan.

A committee prepared a draft statement that was presented to the Faculty Senate in April 2004. Revisions were made in light of comments received at that meeting. The revised draft statement (dated 6/15/04) was then circulated for comment to the entire faculty, the deans and Administration, the department chairs, and the program directors. The comment period lasted 6 months, during the last half of which the Dean of Faculty's office sent three separate e-mails urging Senators, deans, department chairs and program directors to discuss the draft with their faculties. In addition, at two Senate meetings in Fall 2004, Senators were reminded of the

⁶ The functions of LAC are described in footnote 39 infra.

pendency of the comment period. The original closing date for comments (mid-October 2004) was extended to mid-November. The committee received several comments from departments and individual faculty, and reviewed and considered all comments received.⁷ The committee also met with Vice–Provost Robert Richardson to get updated information on how the University is treating corporate sponsorship arrangements that have certain characteristics of SCAs but do not involve large dollar amounts or multiple departments/units. Based on all this information, the committee revised the 6/15 draft to produce this Statement, which was presented to the Faculty Senate at its April 2005 meeting.

How Does This Statement Align with the Relevant Administration and Trustee Documents?

On many important issues, the Faculty, the Trustees and the Administration have arrived at similar conclusions, and such consensus is encouraging. This Statement, however, addresses several points not covered in any of the current Administration or Trustee documents. Moreover, in a small but significant number of instances, this Statement takes a position that is, or may be, ⁸ at variance with the position taken in the Plan. Such instances are flagged in the text below.

It is hoped that this Statement will form the basis for even broader consensus about applicable principles and practices among those responsible for targeting potential corporate partners, negotiating the terms of SCAs, giving final approval to the agreements, and overseeing their implementation.

What is the Function of This Statement?

This Statement has three principal functions:

- To provide recommendations that ought to be incorporated, in mandatory form, into the final version of the general University policies and procedures to govern SCAs, as well as into individual SCA agreements
- To govern faculty review of proposed SCA agreements and ongoing SCA oversight, as undertaken by LAC or whatever other faculty committee may be charged with these functions
- To assist individual faculty involved in SCAs in thinking about the academic freedom, integrity, and openness implications of these arrangements for themselves, their colleagues, their students, and the university community as a whole

⁷ These comments can be found at http://web.cornell.edu/UniversityFaculty/. Identifying information about individual authors has been deleted.

⁸ Sometimes, the text of the Plan is *capable* of being interpreted in a way consistent with this Statement, but inconsistent interpretations are also possible.

What Is the Intended Relationship Between the General Principles and the Accompanying Text?

The lettered statements are overarching principles – usually rooted in concerns about academic freedom and integrity – that form the main normative framework. The numbered statements are more specific expressions of these principles that give particular guidance in the SCA context. The accompanying text provides both discussion of the substantive values and concerns involved, and more detailed examples. This text should be used along with the lettered and numbered statements as an integral part of their meaning and application.

To What Sort of Sponsorship Arrangements Does This Statement Apply?

As previously noted, the University Plan defines an SCA as "a comprehensive, formally managed company-university agreement centered around a major, multi-year, financial commitment involving research, programmatic interactions, intellectual property licensing, and other services."

Obviously, some of these terms are indefinite – if not vague – and the provisions of this Statement are intended to apply to sponsorship arrangements involving a private, for-profit partner that fall within the intent of this definition, whether or not they are formally labeled an SCA. Moreover, developments since the Plan was written suggest the possibility that smaller-scale arrangements involving sponsorship by for-profit corporations may have characteristics of SCAs (e.g., negotiation by central Development); these arrangements may even be described as "small" SCAs, or as being "like SCAs." In such cases, this Statement can provide useful guidance for structuring and managing such arrangements, even though they are not formally within its scope.

This Statement recognizes the possibility of two types of SCA, the different dimensions of which call for somewhat varied procedural protections. The term "Broad SCA" refers to those agreements that involve research questions relevant to a potentially large group of faculty whose precise membership can not be easily specified in advance. All of the provisions of this Statement apply to Broad SCAs. The term "Narrow SCA refers to those agreements in which a small number of specific faculty have been identified in advance as the relevant researchers. Because it is clear from the outset whose research will be funded under such agreements, Section D (protecting academic integrity and enhancing fairness in the funding process) does not apply to Narrow SCAs.

What Sort of Sponsorship Arrangements Are NOT Intended to Be Governed By This Statement?

This Statement is consistent with a larger framework of policies and practices established by (among other sources) the Faculty Handbook, the University Conflicts Policy, and the various regulations administered by the Office of Sponsored Programs. Therefore, many of the principles stated here will apply **because of these other sources** to all sponsored research – and, indeed, sometimes to all research. However, this Statement does not **itself** govern research arrangements that do not meet the Plan definition of an SCA.

Specifically, this Statement does not apply to:

• research sponsored by a government agency; or

- research sponsored by not-for-profit entities; or
- for-profit-corporate research sponsorship that is episodic, negotiated individually by specific faculty, or otherwise not reasonably within the Plan definition of an SCA.

Obviously, line-drawing may be difficult in some cases but, as with the Plan itself, the intent of this Statement is not to alter the operation of the vast majority of existing sponsorship arrangements.

Why Distinguish Between SCAs and Other Forms of Sponsored Research?

As just noted, many of these principles and practices discussed in this Statement are germane to all sponsored research – and, in some instances, to all research. What this Statement provides for SCAs is: (1) a more contextualized consideration of how academic freedom and integrity concerns may be implicated; and (2) a more elaborate set of procedural devices to ensure and monitor compliance. (Note that some of these procedural devices – e.g., the Joint Steering Committee and the RFP process – are originally conceived by the Plan, not by this Statement). This additional attention and layer of regulation is justified, quite simply, by the additional pressures and temptations created by SCAs.

Consider two situations. In the first, a member of the Engineering faculty is receiving \$250,000 from an automobile manufacturer to research more efficient fuel cells. In the second, a department is receiving \$2 million a year for 5 years from a pharmaceutical company to identify the potential for a naturally occurring bioactive molecule to demonstrate anti-carcinogenic activity. The latter situation may result in a re-focusing of laboratory space, faculty effort and graduate student research within the department, as well as the need to limit communications between participating and non-participating faculty and graduate students to protect proprietary knowledge, and a stronger-than-usual preference for obtaining positive results in order to secure future funding (as compared, for example, with NIH funding). It is not that the principles of academic freedom and responsibility, or the obligations to avoid conflicts of interest, are different in these two cases. Rather, the concern is that in the latter case the essential quality of academic independence from the sponsor is more difficult to maintain at an *institutional*, as well as individual, level, and the source of funding may create undesirable effects on intellectual exchange within the department. Therefore, more formal decisional processes and oversight mechanisms are appropriate as continual self-checking and self-correcting mechanisms.

Some may argue that all forms of sponsored research should be identically regulated. The fact remains, however, that Cornell has a history of successfully supporting certain forms of governmentally and privately sponsored research without undue sacrifice of academic freedom and integrity. SCAs, on the other hand, are new for us. A range of respected academic voices agrees that large-scale research partnerships between universities and for-profit corporations should be approached with care. In the circumstances, giving special consideration to the principles and practices that should attend these alliances seems appropriate.

⁹ For some sources, see Appendix D.

GENERAL OBSERVATIONS

Historically, research universities and for-profit corporations have had very different goals, and very different ways of organizing to achieve those goals. The goals of the research university have characteristically included the creation of new knowledge and its broad dissemination. The university typically pursues these goals by affording faculty the freedom to define their own research agendas, and by protecting unrestricted access to the results of scholarship and research. The primary goal of the for-profit corporation has characteristically been to generate a return on investment for its shareholders. The corporation typically pursues this goal by channeling the efforts of its employees towards the objectives defined by corporate leadership, and by utilizing the intellectual property its employees produce for commercial purposes.

Despite these distinctive characteristics, Cornell has long appreciated the possible benefits of collaboration between the university and the corporate sector. Whether expressed in Andrew Dickson White's revolutionary commitment to pairing technological with classical education, or in the land grant mission to couple research with the practical education of society, Cornell has a distinguished history of working with both private and public research sponsors. At the same time, however, it is equally part of Cornell's history to guard academic values jealously. For example, it has refused to sacrifice public access to new knowledge by permitting classified research on campus. ¹⁰ It has been a strong proponent of peer review in allocation of research funds, declining offers of earmarked funding from Congress that lacked this hallmark of academic integrity. In each instance, Cornell has refused to compromise the values of open access and research autonomy in exchange for financial support.

Both strands of Cornell's history – an established, richly varied practice of corporate sponsorship of research *and* a distinctively rigorous commitment to academic integrity and openness – are relevant in thinking about SCAs. In one sense, SCAs are "merely" an extension of what we are already doing. In a very important sense, however, the commitment to pursue SCAs is a significant new step for Cornell. Indeed, were this not so, it is hard to understand why the Administration and the Trustees expended so much time and effort in researching the idea, discussing it among themselves and with various constituent groups, and developing the Plan and the other documents specific to SCAs.

The Faculty both appreciates the need to find new sources of support for the research mission of Cornell and applauds the creativity and initiative the Administration has shown in

See Cornell University Guidelines on Sensitive and Proprietary Research, adopted by the Cornell Research Council on May 20, 1985, reproduced in Faculty Handbook at 91 ("Given the open nature of Cornell University, research projects which do not permit the free and open publication, presentation, or discussion of results are not acceptable. ... In particular, research which is confidential to the sponsor or which is classified for security purposes is not permitted at Cornell University.")

pursuing the SCA idea. At the same time, Faculty opinion is divided about whether, in the end, SCAs will benefit the university. Some fear that the corporate and university cultures are too incommensurate for true partnership. Others are more optimistic and believe that mutually beneficial collaborations are possible without compromising Cornell's academic values and mission. Not surprisingly, this division mirrors the larger debate within the academy about the impact of various sorts of sponsorship on academic freedom and the breadth and integrity of research. (Those wishing to explore this debate will find a sampling of the literature in a bibliography attached as Appendix D.)

In any event, there is broad Faculty agreement that SCAs must be carefully managed at all stages: negotiation, initial implementation, ongoing oversight, post-hoc assessment and, if warranted, policy and practice modification. Attention to the principles and practices of this Statement will help ensure that Cornell retains its academic integrity as it enters into these new collaborations. Particularly important are the recommendations concerning monitoring and evaluation of the SCA experience. Some academic institutions have apparently done SCAs well; others have had well-publicized problems. But there are extraordinarily few reliable data and rigorous assessments of the actual impact of SCAs on research quality and academic culture. Ensuring that such data are being collected and such assessments are occurring here will go a long way towards alleviating Faculty concerns.

PRINCIPLES & BEST PRACTICES

TO BE APPLIED DURING THE

TARGETING, NEGOTIATION, APPROVAL, IMPLEMENTATION, AND OVERSIGHT OF STRATEGIC CORPORATE ALLIANCES

A. THE POWER TO CHOOSE RESEARCH TOPICS FREELY AND THE ABILITY TO PUBLISH RESULTS PROMPTLY, WITHOUT REGARD TO OUTCOME, ARE BASIC ELEMENTS OF ACADEMIC FREEDOM.

1. Research Autonomy Should Be Safeguarded. 12

MIT is a principal example of the former; Berkeley and the Novartis arrangement, the classic case of the latter. (Articles on Novartis, including a citation to the recently released external study, can be found in Appendix D). The difficulty is that neither of these is a sensible model for imagining how SCAs would look at Cornell.

As noted above, MIT has cultivated SCAs for over half a century and now gets almost half of its corporate sponsorship in this form. It is difficult to imagine Cornell, with its many colleges' far more diverse scholarly agendas, ever developing such extensive research integration with private industry.

The Novartis arrangement was only a single venture, but of such massive scale that the corporate sponsor effectively bought almost all the research output of an entire department for 5 years. This level of sponsorship is, perhaps, just within the limits of the imaginable here – but, at the same time, the Berkeley/Novartis partnership has become the textbook example of how NOT to do an SCA. Only unimaginable ineptitude could lead a university now to agree to the sort of terms Berkeley accepted then.

¹² Compare Trustee Doc: Considerations & Principles ¶ II.1("The academic independence of the University and the integrity of the Cornell name will be paramount.")

Autonomy in selecting the topics and direction of research is a defining distinction between holding a faculty appointment, and working as a non-academic employee or as a consultant for hire. Obviously, no faculty member or graduate student should be coerced into participating in any project funded by an SCA.¹³ But research autonomy will not be preserved merely by prohibiting direct coercion. Rather, the entire circumstances of the department/program need to be evaluated to ensure that there remain sufficient institutional resources and support to allow the flourishing of research not allied with the SCA.

To be sure, constriction of research freedom by the pressure of donor preferences is not unique to SCAs. Unless a gift is unrestricted, sponsored research (public and private) always forces the researcher to choose a project of interest to the sponsor. However, the potential magnitude and comprehensiveness of SCAs substantially enhances the threat. Therefore, the key question is whether the SCA occupies so much of the department's/program's potential research capacity that it crowds out non-conforming research agendas.

An SCA should be approved only if faculty within the department/program will, as a practical as well as theoretical matter, retain a sphere of freedom to pursue research topics of their own choosing – either within the SCA or by seeking alternative support for such projects. Factors relevant to this assessment include:

- (a) the proportion of department/program faculty expected to receive all or most of their funding through the SCA;
- (b) the magnitude of any unrestricted funds available within and outside the SCA;
- (c) the proportion of department/program physical, administrative, support, and other resources devoted to SCA projects;
- (d) the narrowness or breadth of the type of projects fundable through the SCA;
- (e) departmental/program commitments to funding diversity of research beyond the SCA;
- (f) whether the success of the SCA has been identified as one of the strategic goals of the department, thereby putting undue pressure on faculty to take part in it;
- (g) likely effect of the SCA on projects/programs traditionally conducted in the public interest.

Particularly in light of these concerns, the faculty commends the administration's commitment to obtaining, in the SCA agreement, both full recovery of overhead costs and a philanthropic portion

12

Compare Trustee Doc: Considerations & Principles ¶ II.4 ("Faculty participation in any alliance, as outlined, will be voluntary."). See also id. ¶ VIII.1.

of funding.¹⁴ The former is essential to ensure that other Cornell resources are not covertly underwriting the SCA and so exacerbating the problem of crowding out. The latter can affirmatively expand the sphere of research freedom if it is channeled to support meritorious projects that do not readily attract sponsors.

The faculty expresses concern over the degree to which the corporate partner's power to terminate the agreement prior to the expected term, or to lower the originally-committed funding level, provides opportunities for covert pressure on faculty research agendas. University negotiators should be extremely careful to protect faculty from such pressure. One possibility is a provision that the partner will pay the salaries of project personnel for a stated period of time in the event that the partner decides to terminate the agreement before the agreed-upon date or decrease the originally-contemplated funding level.

2. <u>RESTRICTIONS ON RELATIONSHIPS BETWEEN FACULTY OR STUDENTS AND</u> "COMPETITORS" OF THE CORPORATE PARTNER SHOULD BE MINIMIZED.

Agreeing to restrict faculty or student relationships with "competitors" of the corporate partner both shrinks the sphere of potential alternative research support and inhibits the public dissemination of knowledge that is a central part of the university's traditional mission. Therefore, such promises should be made only sparingly, and should be very narrowly drawn.¹⁵

In particular:

- (a) The group of "competitors" should be *defined in advance* at the time of entering into the SCA, should be *as limited as possible*, and should in any event include *only for-profit* entities.
- (b) The "when" should be very clear, covering only work done *simultaneously* for the corporate partner and the competitor.
- (c) The "who" should be very clear, covering only the *same* faculty member or graduate student.
- (d) The "what" should be very clear, covering only *similar* work as defined in advance at the time the faculty member's project is funded through the SCA.

Legally justified claims to protect trade secrets or similar proprietary data from competitors can be more broadly recognized, but the scope of claimed protected material should be clearly identified in advance whenever possible.

¹⁴ See Cornell SCA Plan at 6, 8. Restrictions by government or non-profit funding organizations on overhead recovery are not implicated here. See "What Sort of Sponsorship Arrangements Are NOT Intended to Be Governed By This Statement?" supra.

¹⁵ Compare Cornell SCA Plan at 6-7: "Among the benefits Cornell may offer companies are: ... Agreement that Cornell will not enter into research sponsored by competitors that involves the same investigator and similar work."

In a related but more subtle area, it is important that commitments in an SCA to "facilitate" access by the corporate partner to Cornell faculty and students ¹⁶ not become the effective equivalent of discouraging such access to the partner's competitors. A properly conceptualized SCA is a collaboration supporting academic research of interest to the corporate sponsor – it is not a joint venture in which a Cornell department/program becomes a remote research facility "belonging" to the sponsor. It is especially important that arrangements to support faculty research not be permitted to wreak incidental but real harm on vulnerable graduate students.

3. <u>Interference with Publication (Including Delay For First-Look Review)</u> Should Be Minimized.

Any censorship of the content of publication by the corporate partner (beyond legally justified claims to protect trade secrets or similar proprietary data) is obviously unacceptable. However, even "first look" rights can threaten academic freedom and inhibit public dissemination of knowledge. In some fields or sub-fields, timing is so critical that an enforced delay of even 30 days can be significant, and 90 days can be disastrous. Moreover, the right of delay is susceptible of being misused to waylay undesirable results.

Therefore, granting "first look" rights should be understood as undesirable from the University's perspective. ¹⁷ Rather than being routinely offered as part of an SCA, ¹⁸ they should be regarded by University negotiators as a *significant* concession that will made only for good and sufficient reason. Moreover,

(a) To minimize disputes over publishability and to protect graduate students, the scope of claimed proprietary or other protected material should be clearly identified in advance whenever possible.¹⁹

¹⁶ See Cornell SCA Plan at 7: "Among the benefits Cornell may offer companies are: ... Facilitated access to facilities, faculty and students."

¹⁷ Compare Cornell University Copyright Policy (adopted by Board of Trustees Executive Comm., 6/28/90) ("As a matter of principle and practice, the University encourages all members of the Cornell community to publish without restriction their papers, books, and other forms of communication in order to share openly and fully their findings and knowledge with colleagues and the public.")

 $^{^{18}\,}$ See Cornell SCA Plan at 6-7: "Among the benefits Cornell may offer companies are: ... First look at discoveries."

¹⁹ Compare Cornell Guidelines on Sensitive and Proprietary Research , Fac. Hand. at 91 (" Such information [i.e., proprietary] must be identified as such in writing when transmitted and the condition of its acceptance specified.")

- (b) If first look rights are given, they need to be accompanied by conditions and safeguards that should, at a minimum, ²⁰ include the following:
 - (i) separate identification of each medium (journal publications, external presentations, dissertations, etc.) included in first-look review;
 - (ii) such rights should never extend to work beyond that funded directly through the SCA;
 - (iii) the corporate partner should to be urged to develop a rapid clearance procedure (i.e., considerably shorter than 30 days) for time-sensitive material and circumstances such as external presentations;
 - (iv) the ability of graduate students to present material in a timely and effective fashion in connection with seeking employment or another research position needs to be protected even if the involved faculty are willing to delay their own presentations and publications;
 - (v) the corporate partner should give explicit written assurances in the SCA agreement that the right to delay will not be invoked for the purpose of temporarily suppressing undesirable results;
 - (vi) exercise of the right to delay beyond 30 days should be justified in writing by the corporate partner²¹ and monitored by the Joint Steering Committee (see Section C) to ensure that it is not being used as a means of censoring results;
 - (vii) the right to delay should in no event extend beyond 90 days.²²
- 4. <u>Licensing of Inventions Derived from SCA-Funded Work Should Always</u>
 <u>Reserve Academic Use & Distribution Rights, and Should Be Non-Exclusive to the Extent Reasonably Possible.</u>

Cornell has repeatedly reaffirmed its fundamental commitment to faculty "shar[ing] openly and fully their findings and knowledge with colleagues and the public," and has recognized that "the

²⁰ Regulations from the OSP may impose additional limitations on first look rights.

²¹ Compare Cornell Guidelines on Sensitive and Proprietary Research, Fac. Hand. at 91 ("Beyond the thirty days, delays of up to three months are acceptable on the basis of *a formal request* from the sponsor.") (emphasis added)

²² Compare Current Cornell Principles (undated) No. 3 ("Reasonable delays would be permitted for review for confidential company information, patentable subject matters and, if appropriate, preparation of patent applications. In no case will the total delay exceed 90 days.")

²³ Cornell University Copyright Policy, General Statement.

University's primary obligation in conducting research is the pursuit of knowledge for the benefit and use of society."²⁴ Moreover, it has acknowledged its obligation "to seek assurance that any patent right be administered consistent with the public interest."²⁵

In light of these commitments and obligations, licensing of inventions derived from SCA-funded work should, whenever possible, take the form of non-exclusive licenses to the corporate partner to use university-owned patents. By giving the licensor a monopoly over use of the patented invention, exclusive licensing inevitably interferes with full and open sharing of the results of academic research. Moreover, unless circumstances are very carefully assessed, it may allow the principal beneficiary of the patent right to become the private, rather than the public, interest.²⁶

In the event that exclusive licensing rights are given to the corporate partner, such rights should be as narrowly drawn as possible. For example, they should cover the fewest number of patents, for the shortest period of time that can be negotiated.

Most important, all SCA agreements should include a provision protecting Cornell's right freely to use and distribute research methods and results to academic researchers at Cornell and other academic settings. Even if an exclusive license is granted, these rights to use and distribute methods and results for academic research should be retained.²⁷

5. ANY INTERFERENCE WITH ACADEMIC FREEDOM SHOULD BE REPORTED TO THE DEAN OF THE FACULTY, WHO IN ADDITION TO COUNSELING ORDINARY REMEDIES WILL ENSURE THAT SUCH REPORTS ARE TRACKED.

Any faculty member who experiences interference with academic freedom in connection with an SCA should seek the assistance of the Dean of the Faculty. Moreover, "[i]ndividual faculty members are encouraged to speak out on behalf of a fellow faculty member's academic freedom,

²⁴ Cornell University Patent Policy, ¶ A.1.

²⁵ Id. ¶ A.2.

The Patent Policy recognizes that "the development and marketing of inventions resulting from University research so as to reach a public usefulness and benefit ... may require various forms of agreements including the granting of exclusive licenses." Id. \P F. The challenge, of course, is accurately predicting the circumstances in which exclusive licensing will indeed be the optimal strategy for developing the invention in the public interest.

²⁷ Compare Cornell Principles (undated) No. 5 ("Cornell will retain the right to practice any inventions for its own research and education purposes, and will retain the ability to distribute any biological materials created under a corporate research sponsorship to other academic researchers.")

²⁸ See Faculty Handbook at 89 (statement on research freedom of faculty, indicating that those who are threatened or harassed in the exercise of this freedom "should seek assistance through the Dean of Faculty.")

either individually or through the Faculty Senate and its committees"²⁹ or by seeking the assistance of the Dean of the Faculty.

In such circumstances, the Dean of the Faculty should counsel the faculty member as to the range of remedies ordinarily available for such interference. In addition, he/she should (1) report the complaint to the Local Advisory Council (LAC), who should take such complaints into consideration as part of its periodic review of the operation of the alliance (see Section E.2); and (2) ensure that a database is being maintained of such complaints, in order that they may be appropriately considered in assessing the experience under particular alliances and SCAs in general.

B. ACADEMIC FREEDOM ENTAILS THE RESPONSIBILITY TO UNDERTAKE AND PRESENT RESEARCH WITH OPENNESS AND INTEGRITY, AND CONDITIONS HAVE TO BE MAINTAINED IN WHICH FACULTY CAN FULFILL THIS RESPONSIBILITY.

Academic freedom brings with it the responsibility of disinterested integrity in the conduct of research and the publication of results. As the subsequent external review of the Berkeley-Novartis agreement put it, ""The privileges of academic freedom do carry the responsibility of professional ethics and candor." Although this responsibility attends all research, sponsored or not, the comprehensiveness and scale of an SCA and the pervasive influence of the corporate partner may make it particularly difficult to maintain the conditions in which faculty are able, and motivated, to fulfill their responsibility.

1. NO RESTRICTIONS ON REVEALING THE SPONSORSHIP RELATIONSHIP ARE PERMISSIBLE.

No SCA should contain any provision that permits, or even implies, that the corporate partner has the right to forbid faculty or graduate students from disclosing SCA sponsorship of research. Oversight of SCA implementation should be sensitive to any evidence that the corporate partner (or its on-site employees) is exerting pressure on faculty or graduate students not to disclose sponsorship.

Forthright disclosure of the sponsorship of particular research is one of the simplest, and best, antidotes for the suspicion that the quality of work has been compromised by the interests of its sponsor. Increasingly, external review organizations, top journals, and even entire disciplines are adopting norms that require disclosure of sponsorship relationships as a matter of course. It may be that Cornell ought consider adopting a university-wide rule in this area, as a way to safeguard the integrity of research that is so essential to the academic mission. Such a norm would protect faculty from pressure not to reveal sponsorship affiliation when publishing results that are

²⁹ Id.

³⁰ Busch, et al, External Review of the Collaborative Research Agreement Between Novartis Agricultural Institute Inc and the Regents of the University of California at 154 (July 31, 2004) [hereinafter "External Review", available at http://www.berkeley.edu/news/media/releases/2004/07/external novartis review.pdf.

counterproductive, embarrassing, or otherwise undesirable from the sponsor's perspective.

2. <u>Multiple Simultaneous Relationships With the Corporate Partner Should Be</u> Carefully Managed.

SCAs pose significant challenges for departments/programs and for individual faculty in maintaining the line between academic independence and corporate employment. These challenges become even greater if the corporate partner seeks to employ faculty as consultants or independent contractors while faculty are also receiving funds through an SCA.

Such simultaneous arrangements have to be very carefully managed, and will need to be avoided unless a clear separation can be maintained between work done as a faculty member of the university (though made possible through SCA sponsorship) and work for hire done for the corporate sponsor. See generally "Cornell University Conflicts Policy, Academic Policies/Responsibilities: Consulting"; Office of Sponsored Programs, "Guidelines for Consulting Agreements." The circumstances of a particular SCA may make it prudent to require the corporate partner to forego entirely such simultaneous, potentially confusing side relationships with faculty receiving support through an SCA. Indeed, experience with SCAs over time may reveal that general guidelines in this area are possible and appropriate.

3. <u>Any Interference with a Faculty Member's Responsibility To Publish Results</u>, Regardless of Effect on the Sponsor, Is Unacceptable.

To be consistent with academic integrity and responsibility, a faculty member's decisions about whether and when to publish results have to be based on objective assessment of the value of the work, using the standards and norms of the discipline – not on perceptions about the likely reaction of the sponsor to publication. Unfortunately, effectively insulating faculty from pressure to behave in ways that will please their sponsor is difficult – especially when the sponsor has committed large amounts of funding to the department/program over multiple years. The difficulties are multiplied when the faculty member has been working side by side with employees of the corporate partner, who understandably share their employer's interests.³¹

At a minimum, the SCA agreement should contain an explicit written commitment that neither the corporate partner nor its employees will attempt to dissuade faculty from publishing results obtained from sponsored research.³² Such a provision at least puts the partner on notice that publication decisions lie solely in the realm of academic judgment, and are an area in which the

Among the duties of the new Director of Corporate Strategic Alliances is "keeping companies fully engaged" by "e.g., facilitating symposia, arranging visits, and placing company researchers in residence at Cornell. [The Director] ... will maintain close communication and coordination with Cornell faculty, and will help bridge any culture gap by exhibiting and encouraging mutual trust and synergy among scientists." Cornell SCA Plan at 8.

³² Compare Cornell Guidelines on Sensitive and Proprietary Research, Fac. Hand. at 91(" Nor will the university enter into any agreements unless the principal and co-principal investigators have the final authority on what is to be published or presented.")

partner has no legitimate role. Beyond this, oversight of the SCA in progress should be alert to any indications that faculty are being induced to engage in self-censorship based on sponsor interests rather than appropriate scholarly norms.

C. DECISIONMAKING AUTHORITY OVER CORNELL RESEARCH HAS TO REMAIN PRIMARILY WITH CORNELL DECISIONMAKERS.

The Plan calls for creation of a Joint Steering Committee (JSC) to manage the SCA.³³ Beyond providing that the JSC will be "led by a Cornell and company representative,"³⁴ the Plan does not specify organizational or operative details of the JSC. Under the Plan, the JSC "will review and select faculty proposals for funding," through a process involving "internal faculty Requests-for-Proposals."³⁵

1. <u>The Management Group Should Contain Non-Participating</u>, as Well As Participating, Faculty.

The JSC should contain some faculty members who are not direct stakeholders in the SCA and who are outside the specific intellectual disciplines of the faculty participating in the SCA. Being themselves outside the funding opportunities of the alliance, their perspective can help provide balance and objectivity, flag potential conflicts and other incipient problems, and prevent the fact or appearance that the enterprise is becoming inbred. Moreover, participation of disinterested faculty gives additional reassurance – both within and outside the department/program involved – that funding decisions will be evenhanded, and that the SCA is being managed with due regard for the values and mission of the university as a whole.

Selection of Cornell JSC members should involve consultation and advice of the Dean of Faculty.

2. <u>Day-to-Day Management of the SCA Should Be Predominantly By Cornell</u> Faculty, Not Corporate Representatives.

One fundamental touchstone can never be lost: This is academic research, not corporate research. ³⁶ If there is a Director of the alliance (see Section D.3), that Director needs to be a

³³ Cornell SCA Plan at 6, 7, 8.

³⁴ Id. at 8.

³⁵ Id. at 8, 7.

³⁶ See Cornell Guidelines on Sensitive and Proprietary Research, Fac. Hand. at 91: The university will accept only sponsored research projects which are expected to further the research and educational mission of the institution. While a sponsor may delineate the areas of research to be supported, the principal and co-principal investigators must have final authority for decisions on the course of the research program within these limits. The principal and co-principal investigators must also have final authority regarding employment of personnel for the project. In particular, research that is subject to a sponsor's approval of personnel is not permitted at the university.

Cornell faculty member. If all management is to be done by the JSC as a committee of the whole, then Cornell representation has to predominate. The corporate sponsor appropriately has a voice in management decisions, but may not have a representative with Co-Director status, and no more than 1/3 of the members of the JSC or any other management group should be corporate representatives. ³⁷

3. <u>Selection of Faculty Proposals for Funding Should Not Be Dictated By</u> Corporate Representatives.

The distribution of alliance funds to Cornell faculty, staff and students should be primarily in the hands of Cornell, not the sponsor.

In keeping with the purposes of the alliance and the interests and priorities of the sponsor as expressed in the RFP, representatives of the corporate sponsor may participate in the selection of proposals to be funded, but this process should be led by Cornell faculty, and corporate representation should not exceed 1/3 of the membership of any selection committee.

D. IN THE CASE OF CERTAIN SCAS ("BROAD SCAS"), OBJECTIVE STANDARDS, PEER REVIEW, AND SOME FORM OF EXTERNAL ACCOUNTABILITY ARE NEEDED TO PROTECT ACADEMIC INTEGRITY IN THE FUNDING PROCESS AND TO ENHANCE FAIRNESS.

Although the subject-matter interests and commercial priorities of the corporate sponsor may appropriately inform the general objectives of the alliance, in the case of "broad SCAs" – those involving research questions relevant to a potentially large group of faculty whose precise membership cannot be easily identifiable in advance of the formation of the SCA – the process for funding research through the SCA should follow traditionally respected academic protocols for proposal evaluation and grant awards. This process includes Requests for Proposals, peer review, and a selection process that seeks to ensure a proper balance in the research portfolio among scientific merit, commercial potential and public interest research.

Note that this entire section does not apply to "narrow SCAs" – i.e., those in which a small number of specific faculty have been identified in advance as the relevant researchers

³⁷ Compare Cornell SCA Plan at 6-7: "Among the benefits Cornell may offer companies are: ... Shared management of the Alliance via Joint Steering Committee."

The 33% formula chosen here is slightly below the 40% corporate membership on the Berkeley-Novartis governing committee. The structure of that committee occurring in one of the most pro-industry SCA agreements we know about) should allay concern that no sponsor will enter an SCA unless it has at least equal representation in – if not control over – the governing body. Indeed, according to the external study subsequently commissioned by Berkeley, the presence of Novartis representatives on the committee originated in the faculty's suggestion rather than the sponsor's demand. See Busch, et al, External Review at 87, note 30 supra.

1. The Joint Steering Committee Should Prepare Requests for Proposals That Specify As Clearly As Possible the Criteria That Will Govern Grant Awards and the Process for Application.

Clear and detailed notice of the criteria and the process for obtaining funds through the SCA serves several purposes. Most obviously, it enables participating faculty to design their proposals as effectively as possible. In addition, it facilitates the job of those who will be reviewing the proposals (see Section D.2). Finally, from an institutional perspective, it is a small but important piece of the transparency that allows external monitoring to confirm that research funding through the alliance has been evenhanded and based on scientific merit. (See Section E.2).

2. Proposals Should Be Evaluated By Non-Participating Cornell Faculty Competent To Assess Their Merit.

Peer review by disinterested scholars remains the premier method of assessing the merit of academic work. Cornell recognizes this in a number of relevant settings; for example, it constitutes internal peer review panels to evaluate proposals for the Affinito-Stewart Grant Program of the President's Council of Cornell Women.

After proposals are submitted in response to the RFP, internal peer review panels of non-participating faculty should be constituted to evaluate their merit. Factors to be considered may include the mission statement of the alliance. These evaluations need not be lengthy; examples of modest-length evaluation instruments exist from other programs. The important point – vital to honoring the principle that we are engaged in academic, not corporate, research – is that genuine, disinterested peer review occur.

3. <u>Funding Decisions Should Be Made In a Way That Enhances Accountability</u>, <u>and Should Be the Subject of Periodic External Reporting.</u>

- (a) The final step in the grant process deciding which proposals to fund should be structured to maximize accountability. This goal could be accomplished by, for example, placing ultimate responsibility in the hands of an alliance Director who is not a member of the JSC and who would make grant award decisions (after receiving the peer review assessments) with the advice and consent of the JSC.
- (b) Whether decisions are made by a Director, the JSC itself, or some other mechanism, a report of funding decisions from each grant cycle, along with the relevant RFP, should be submitted no less frequently than annually to the Local Advisory Council (LAC). (See Section E.2). This report should be sufficiently detailed in describing projects both funded and not funded that LAC can satisfy itself that research support through the alliance has been evenhanded and based on scientific merit.

E THE FACULTY, THROUGH ITS REPRESENTATIVES, SHOULD HAVE A CENTRAL ROLE IN THE APPROVAL AND OVERSIGHT OF SCAS.

Both the "Trustee Document: Considerations & Principles" and the Plan commendably contemplate that LAC will play a key role in review, approval and oversight of SCAs.³⁸ LAC's substantive expertise, its tradition of providing rigorously independent faculty judgment within a constructive working relationship with the administration, and its demonstrated ability to handle sensitive information appropriately, all make it the logical first choice for this role.

Nonetheless, some caution in calling upon LAC is appropriate. This committee already performs a vital service that places heavy demands on the time of its member faculty. ³⁹ If a complex SCA were to be proposed and/or if multiple SCAs were simultaneously to be undertaken, the burden could quickly become overwhelming. The faculty role in approval and oversight contemplated by this Statement is significant, and should not be undermined by entrusting it to a committee which, no matter how well-qualified and well-intentioned, is simply too busy with other important matters to carry it out. Therefore, although this Statement refers to LAC as the faculty committee with responsibilities in this area, entrusting the responsibilities to some other faculty committee might prove necessary.

1. No SCA Should Be Entered into Without the Approval of LAC, Who Should Be Involved Early Enough in the Process That the Agreement Is Not a Fait Accompli. Amendments to an SCA Should Also Receive LAC Approval. LAC Should Report Its Conclusions to the Dean of the Faculty, as Well as to the Appropriate Administration Officials.

Finalization of an SCA should not occur unless and until LAC has reviewed its terms and determined that the SCA – both in concept and, so far as can reasonably be predicted, in likely implementation – is consistent with this Statement and any refinements suggested by practice and experience under it. Moreover, LAC should be involved early enough in the process of attempting to form an SCA that it can have meaningful input in changing problematic elements. This timing issue is a point of considerable sensitivity for several reasons.

Involving LAC early in the process will raise concerns. From the perspective of the negotiators, the period before key terms of the deal are finalized is understandably viewed as highly confidential, volatile, and vulnerable to private leaks or unguarded public statements. Multiplying

 $^{^{38}}$ See Trustee Doc: Considerations & Principles \P VII; Cornell SCA Plan at 5.

³⁹ Currently, LAC performs two principal functions. It advises the administration, through the Vice Provost for Research, on key issues pertaining to the research enterprise at Cornell. Recent examples include review of the Center for the Environment and the Ward Center for Nuclear Sciences. In addition, it reviews proposals and nominations and makes recommendations regarding the relative ranking of Cornell candidates for external grants and awards in cases where the competition is limited to a fixed number of applications or nominations.

participants multiplies risks. From the perspective of the faculty, involving LAC while bargaining

is active poses the danger that LAC will become invested in achieving an SCA. LAC's role as independent reviewer is compromised if it becomes a stakeholder in getting to an agreement.

On the other hand, too-late involvement also carries serious risks. If LAC does not review the proposal until the deal has been effectively struck between the administration and the corporate sponsor, the costs of disapproval become enormous. Considerable time and effort will have been expended by administration and corporate officials (often at the highest levels of both organizations), faculty in the involved department/program will have become invested in going forward, and a great deal of money and other research support is likely sitting on the table. LAC objections at that stage may divide the faculty against itself, and will surely put the faculty and the administration on a high-stakes collision course from which no one benefits.

In arriving at the form and timing of LAC involvement that best balances these various risks, the faculty must largely rely on the administration. The Plan contemplates LAC involvement at the point at which the negotiations team has reached a Memorandum of Understanding (MOU).⁴⁰ An alternative model, that we encourage in the spirit of open and thoughtful faculty consultation, would be a carefully selected subcommittee of LAC who is initially briefed on the target project, who is kept informed by the negotiating team of any significant policy issues as they emerge, and who then can take an informed lead in full committee discussion of the MOU. In any event, subsequent to the MOU, LAC should *also* review and approve the final version of the SCA.

Recognizing that experience and/or external events might prompt changes during the term of an alliance, the Plan provides for the possibility of amendment.⁴¹ The advice and consent of LAC should be sought before any not insignificant amendment is made to an SCA.

After it has made its assessment of the MOU, the final version of the SCA, or any amendments, LAC should communicate its conclusions to the Dean of the Faculty, as well as to the appropriate members of the administration.

2. LAC SHOULD REVIEW THE PERFORMANCE OF EVERY ONGOING SCA ANNUALLY, RECEIVING FROM THE JSC AND/OR THE ALLIANCE DIRECTOR PERIODIC REPORTS AND OTHER INFO AS NEEDED TO PERFORM THIS REVIEW. LAC SHOULD REPORT ITS CONCLUSIONS TO THE DEAN OF THE FACULTY, AS WELL AS TO THE APPROPRIATE ADMINISTRATION OFFICIALS.

It is anticipated that SCAs will enhance Cornell's ability to produce knowledge that is publicly available and promotes other public interests. At the same time, the planned scale and

Cornell SCA Plan at 5. The MOU sets out the "key elements" of a proposed SCA ("the expectations of the parties and the source(s) of alliance funding"), but has not yet been approved by either legal counsel or senior management. Id.

⁴¹ Id. at 6-7.

comprehensiveness of SCAs may produce a variety of unanticipated consequences in practice – consequences, for individual faculty and for departments/programs, that differ not only from those produced by other forms of sponsored research, but also from one alliance to another. A great deal of uncertainty attends both the positive and the negative potential outcomes – in part because little systematic research has been conducted at other universities on SCAs, and in part because the design of SCAs can vary widely. No matter how carefully the faculty, the administration, and the trustees attempt to manage these outcomes through guidelines produced ex ante, we can be confident that alliance implementation will be a work in process that needs refinement in light of experience, in order to maximize the hoped-for benefits of SCAs and minimize or mitigate the unanticipated negative consequences.

Therefore, in addition to approving the initial agreement, LAC should review the actual experiences in the course of implementing the SCAs and communicate its findings to the Dean of the Faculty as well as appropriate members of the administration.

To conduct its review, LAC should rely upon the following:

- Reports, at least once a year, from the JSC and/or alliance Director concerning funding decisions (see Section D.3), and any other material LAC needs to determine that the SCA is being implemented consistent with this Statement and any subsequent refinements suggested by practice and experience under it.
- Any complaints forwarded from the Dean of the Faculty under Section A.5, along with the results of any university processes that have been invoked to resolve those complaints.
- Three years after the formation of the SCA, LAC should request an independent review by a team of researchers who are qualified and experienced in mixed methods evaluation, and who are not associated with either the SCA or the corporate sponsor. The researchers should assess the impact of the SCA on the goals and functions of the University as a research and teaching institution. Responsibility for the design of the evaluation should rest with this team, not with LAC or the administration. This team should have access to all the material available to LAC. It is contemplated that the team will interview participating and non-participating faculty and students in the involved department/program. The team should report to the LAC, the Dean of Faculty, and appropriate members of the administration; at least a summary of all principle findings and conclusions and if possible the entire report should be made available to the university community. See Section F.

The Plan acknowledges this by contemplating the creation of a new administrative position, the Director of Corporate Strategic Alliances, although the focus of this position may be more on facilitation of alliance activities than oversight of them. See p. 8. See also Trustee Doc: Considerations & Principles ¶ IX ("The plan, and any alliances, will include provisions that will require periodic review and will allow the University to implement modifications or terminate alliances that were not judged to be successfully furthering Cornell's research or educational missions.")

3. <u>TO PERFORM ADEQUATELY THE FUNCTIONS OF APPROVING SCA AGREEMENTS AND REVIEWING THEIR IMPLEMENTATION, THE COMPOSITION OF LAC SHOULD BE BROADENED.</u>

To the extent that it is engaged in review of SCA-related matters, LAC should be expanded to include significant representation from some or all of the following groups of faculty: (1) natural scientists with no personal stake in the alliance funding opportunities; (2) social scientists; (3) ethicists; and (4) researchers with experience in human and animal subjects research protocols.

Just as participation of disinterested faculty on the JSC helps expand the viewpoint of day-to-day alliance management (see Section C.1), so broadening the composition of LAC will enhance the range of perspectives that are examining SCA proposals and reviewing implementation. Broadening the expertise base of LAC review in this way could have very specific benefits. For example, private research is not covered by current federal law on human subjects research; therefore, the ramifications of the complex, and sometimes time-consuming, compliance procedures in this area may be outside the contemplation of the corporate partner. Ensuring that someone on LAC has this expertise could help bridge a potentially significant cultural gap. ⁴³

More important, however, is the general benefit of bringing representatives of the larger university community into the process of SCA review, approval, and oversight. The addition of social scientists and ethicists, for example, will better position LAC to assess the alliance's ongoing impact on the department/program and on participating (and nonparticipating) faculty and graduate students.

4. <u>In addition to Evaluations of Each Specific SCA, Broader Studies of the SCA</u> Experience at Cornell Should be Undertaken.

In addition to the evaluations described in Section E.2:

- (a) The Dean of the Faculty should annually convene a confidential meeting of the non-participating faculty serving on all the JSCs of SCAs that, in his or her judgment, are still operative. The faculty should discuss their observations and experiences from their JSC service and issue a report to LAC which may, if appropriate, include recommendations. A summary of this report will be presented to the Senate.
- (b) A more comprehensive longitudinal study of the SCA experience should be initiated to examine broader issues related to potential crowding-out of public research, effect on the nature and extent of intellectual interchange among participating and non-participating faculty and students, displacement of funding from other sources, disproportionate growth across unit, impact

We assume that every SCA agreement will contain an explicit statement that research conducted under the alliance will comply will all rules, policies, and protocols applicable to other Cornell research. Of course, it is a wholly separate matter whether the corporate sponsor *knows* the full extent of these rules, policies and protocols – and appreciates the practical implications they may have for how research is done and published in academia.

on external relations, and other issues. The dearth of empirical information on these matters is one of the factors impeding informed and reasoned discussion of SCAs at Cornell and elsewhere, and this study can become a resource for Cornell and the larger set of organizations interested in evolving public-private relations in the production and control of knowledge. According, this study and the other activities noted above should be funded as a charge to overhead of SCAs.

F. ONCE AN SCA HAS BEEN FINALLY APPROVED BY CORNELL AND THE CORPORATE PARTNER, THE TERMS OF THE SCA SHOULD BE MADE AVAILABLE TO THE CORNELL COMMUNITY.

Transparency and openness are significant steps towards reassuring those who fear the effect of SCAs on Cornell's tradition of research autonomy and integrity. As a former chair of LAC said in discussing his committee's report with the Faculty Senate, "We think the way to deal with these potential fears, from our committee's point of view is..., 'Let there be light'." Many of the practices set forth in this Statement implement this general principle.

Allowing the community to see for itself what is permitted – and forbidden – under the terms of an alliance is essential. Otherwise, an undertaking that will inevitably be the subject of considerable interest and debate may become the object of uninformed speculation and wild rumor. Obviously, confidentiality is essential while negotiations are pending. Once the agreement is final, however, the administration should work hard to overcome any reluctance, on the part of the corporate partner, to make the terms of the agreement public to the university community. Openness about such matters may be a cultural difference about which the corporate partner will require education; nonetheless, it has such a high value in this environment that the administration should be insistent.

INDEX [Page numbers in <u>italic</u> typeface indicate location in footnotes]

A	Definition, SCA
	Director of alliance
Academic freedom	Cornell faculty, requirement
Complaints about interference with16, 24	Duty to report to LAC24
Database of complaints to be maintained17	Grant award decisions, role in21
Dean of Faculty's role in protecting17	Not a JSC member21
First look rights and	Disclosure of sponsorship provisions17
Research autonomy as element of	E
Responsibility that accompanies	L
Academic integrity	Evaluations recommended 24. See Monitoring
Publication of results regardless of effect on	Annual meeting of non-participating faculty from
sponsor	JSCs 25
Anti-competitor clausesSee Competition-restricting	Comprehensive longitudinal study26
clauses in SCA agreements	Review by independent experts24
В	F
Berkeley 11	Faculty Statement of Principles & Best Practices
Berkeley-Novartis external review17, 20	Arrangements Covered
Broad SCA	Arrangements Not Covered
External review of funding decisions4, 21	Function
Funding process in 20	Relationship to other university policies8
Peer review of funding proposals required3, 21	Tex <i>T</i> accompanying principles, meaning of2, 7
RFP with objective standards required	First look rights14
	90 day, unwaivable maximum15
\boldsymbol{c}	Guarantee of no delay to suppress content15
Censorship	Limited to work funded directly thru SCA15
Delay to suppress undesirable results	Necessary conditions that must accompany grant of
Classified research, prohibition on campus	15
Committee	Rapid clearance procedure, importance of15
Director of alliance and grant awards21	Significant bargaining concession14
Competition-restricting clauses in SCA agreements	Written justification for > 30 days15
Advance definition, importance of	Function of Faculty Statement2, 7
Limited to for-profit competitors	
Limited to identical faculty or students	\boldsymbol{G}
Limited to similar work	Goals of university vs. for-profit corporation10
Limited to simultaneous work	
Comprehensive longitudinal study	I
Conflict of interest	Independent contractor, working as while getting SCA
Consultant, working as while getting SCA funds 18	funds
Crowding out	Turido
	J
D	Joint Steering Committee
Dean of the Faculty	Cornell membership
Academic freedom complaint, duty to forward to	Cornell vs. corporate membership20
LAC17, 24	Dean of the Faculty role in selecting19
Academic freedom complaints, role in17	Duty to report to LAC24
Database of academic freedom complaints, duty to	Monitoring first look rights to ensure no censorship
maintain17	
JSC member selection, role in	RFP preparation, role in
Meeting of non-participating faculty on JSCs, duty	Selection of proposals for funding19, 20
to convene annually25	JSC See Joint Steering Committee

L	P
LACSee Local Advisory Council	Peer review
Licensing of inventions	Objective standards in RFP process, importance to
Exclusive must be narrowly drawn16	21
Non-exclusive whenever possible16	Role in Broad SCAs21
Right to academic use must always be reserved 16	Pressure
Local Advisory Council	Competitor access, not to allow students14
Academic freedom complaints, considering as part	Sponsorship, not to disclose17
of periodic review of SCA17	Suppression of undesirable results18
Alternative possible designee for SCA functions 22	Undesirable results, delay publication15
Amendments to SCA, approval needed22, 23	Public reports
Approval of SCA, necessity for22	Independent expert review of SCA24
Assessing restrictions on contacts with competitors	SCA agreement26
of SCA partner13	•
Dean of the Faculty, reports to23, 24	R
Duty to request independent expert review of SCA	Requests-for-ProposalsSee RFP process
24	Research autonomy12
First look rights, factors to consider if SCA	Factors relevant to safeguarding12
agreement includes	Unilateral termination power as threat to13
Funding decision report, receipt and review21	Research sponsored by a government agency8
Membership to be expanded	Research sponsored by not-for-profit entities8
Negotiation of SCA, involvement in22	Review by independent experts24
Non-SCA functions	RFP process
Research autonomy assessment in SCA approval. 12	Accountability and transparency, importance of21
Review of SCA experience24	Objective standards
Role in review, approval and oversight of SCAs 22	Peer review evaluation 21
Sponsorship provisions, permissible content 17	
Subcommittee for SCA negotiations	\boldsymbol{S}
	SCA agreement, terms of
M	Desirable
Management of SCA	Advance identification of proprietary material.14
Cornell influence must predominate20	Philanthropic funding13
Selection of proposals for funding20	Rapid clearance procedure for time-sensitive
Memorandum of Understanding	materials15
Definition	Termination clause that minimizes research
MIT5, 11	agenda manipulation
Monitoring11	Prohibited
Database of academic freedom complaints 17	Anti-competition provision exceeding same
Objective standards in RFP process, importance to	faculty/students doing simultaneous, similar
21	work for for-profit competitors13
Reports from each funding cycle21	First look rights > 90 days
Self-censorship by faculty, alertness for19	Sponsorship disclosure ban17
MOUSee Memorandum of understanding	Required
-	Compliance with all Cornell policies25
N	First look rights in separate identified media and
Narrow SCA8	only work funded by SCA15
Peer review does not apply to	Full overhead recovery
RFP process does not apply to	No coercion of faculty/student to participate12
Novartis	No interference with publication
	No use of first look rights to delay undesirable
0	results
Overhead, importance of full cost recovery12	Reserved right to academic use of inventions,
o	etc

Scope	2, 8
Selection of proposals for funding	
Annual reporting to LAC	21
Cornell influence must predominate	20
Self-censorship by faculty, dangers of	19
Sponsorship of research must be disclosable	17
Strategic corporate alliance	
Arrangements like	8
Careful management, importance of	
Definition	
Management control	19
Monitoring, importance of	
Review by independent experts	

Types of	8.
Students	
Access to SCA partner's competitors, right to1 First look right exception for employment, etc.	4
presentations1	15
First look rights and protecting1	4
Importance of protecting1	4
Restricting relationships with SCA competitors1	3
T	
Termination clauses in SCAs1	13
Transparency	26

APPENDIX A

Cornell University Strategic Corporate Alliance Plan (7/30/03)

Cornell University Strategic Corporate Alliance Plan

Objective: To leverage access to Cornell University intellectual capital, including faculty research, into major corporate alliances leading to competitive opportunities for select companies and financial support for faculty research and related infrastructure.

Goal: Secure strategic corporate alliances for the Cornell New Life Sciences with one or more companies in each of five initial target industries. Also, capitalize on non-New Life Science alliance opportunities where Cornell has unique strengths.

Definition: A strategic alliance is a comprehensive, formally managed companyuniversity agreement centered around a major, multi-year, financial commitment involving research, programmatic interactions, intellectual property licensing, and other services.

Observations:

- Cornell's sustained research expenditures (\$465M in 2002) represent to prospective partners significant investment, a strong infrastructure, committed administration, and potential commercial opportunity, especially in genomics, proteomics, bioinformatics, pharmacogenomics, devices and plant science.
- Cornell's planned investment (\$500M) in the New Life Sciences infrastructure and new faculty represents an opportunity to attract, interest, and engage companies at a high level over a sustained period.
- Cornell can offer to companies cutting edge-basic research over a broad landscape (e.g. mammalian, microbial, plant, and computational genomics.); unique strengths especially in plant science, materials, and nanotechnology/nanobiotechnology; unique facilities; a strong track record of interdisciplinary research including multi-disciplinary national research centers, e.g., Biotechnology Institute, Center for Materials Research, High Energy Synchrotron Source, Nanoscale Facility, Nanobiotechnology Center, Theory Center, Developmental Resource for Biophysical Imaging and Optoelectronics; and a reputation for outstanding scholarship and research.
- Companies are willing to engage in company-to-company and company-to-university alliances to share costs, increase R&D productivity, boost pipelines, acquire new technology, and supplement internal research, e.g., Eli Lilly's strategy of "innovation without walls."
- Companies have an increasing need for the "new life scientists" and Cornell is the nation's largest producer of undergraduates who go on for PhD's in the Life Sciences (National Science Foundation).

Confidential- Not for Distribution outside Cornell Revised: 7/30/03

- While traditional single academic scientist-to-industrial scientist relationships
 will continue, a focused effort to secure broader, strategic alliances will
 benefit larger numbers of faculty and improve their combined research
 infrastructure. Faculty research support is foremost but philanthropic funding,
 including term professorships, graduate fellowships, new or renovated
 facilities, and equipment, is feasible when it supports the aims of an alliance.
- The Alliance Plan should include the Weill Medical College in alliances that touch upon the life sciences or human health care. Cooperation and collaboration between the Medical College and Ithaca are essential in order to maximize the intellectual and economic benefits of relevant alliances and make an alliance more appealing to prospective company partners.
- The leadership of all colleges should be committed to the basic principles of strategic alliance development, implementation and management processes.
 The synergy inherent in Cornell's interdisciplinary structure and supportive climate is a great advantage.
- Universities can secure large multi-year research-based agreements from companies in industries ranging from pharmaceuticals and biotechnology to automotive and computing, but compelling science and cultural blending are central to the success of such alliances. Since Cornell has minimal long-term company bioscience relationships, the quality of its science and the potential for commercial advantage will be decisive factors in developing relationships.
- A university-company alliance must be based upon what is needed by the company's businesses; however, the company's needs do not dictate the university's research interests or directions. The challenge is to identify and match the company's strategic needs and Cornell's research strengths.
- Acquiring, using, and improving a partner's advanced equipment should be a consideration in potential alliances with companies.
- The biotech industry is gradually consolidating. Biotech to biotech alliances are increasing more rapidly than biotech - to - pharmaceutical alliances. With patent expirations and less than robust pipelines, pharmaceutical companies have acquired or formed alliances with biotech firms which are themselves advancing many products to later stages of development.
- Pharmaceutical alliances with biotech companies generally involve a small up-front payment by the partner followed by milestone-based payments and royalties or profit-sharing. University agreements involve multi-year funding with potential for intellectual property licensing.
- Genomics and drug discovery are popular areas for biotechnology alliances.
 Alliances in pharmacogenomics, proteomics, and informatics are rising
 steadily. Both U.S. and European pharmaceutical companies are active in
 establishing alliances with biotechnology companies. Most biotechnology
 companies do not have the resources to fund university alliances.

I. Organization

Form a Cornell Strategic Corporate Alliance Team to secure strategic alliances with companies, negotiate the agreement, manage post-agreement activities, negotiate intellectual property licensing, and maintain the relationship.

- Research -- Robert C. Richardson, Vice Provost for Research
- Strategy Development -- Inge T. Reichenbach, VP, AA&D
- Alliance Negotiations Richardson/ Reichenbach/ Adler/ President, OTL
- IP Negotiations -- President, Office of Technology Licensing and Economic Development
- *Management* -- Kraig Adler, Vice Provost for Life Sciences
- Legal Counsel James J. Mingle, University Counsel
- Staff Support Nick Komanecky, Christopher Miller, Denise Clark

Staff work will be conducted by the Office of University Corporate Relations. When alliances are secured and project management is required, a Director of Corporate Strategic Alliances will be hired and staff added in proportion to need.

Engage Two Advisory Groups:

- (1) **The Research Subcommittee of the Board of Trustees** provides advice on the overall strategic plan from company identification, contacts, and negotiation through licensing and legalities. Subsequent to the initial Plan draft, the Subcommittee issued Considerations and Principles Regarding Strategic Alliances. (See Appendix A)
- (2) An ad hoc *Industry Advisory Group* comprised of Cornell alumni possessing industry-specific knowledge will counsel the Cornell team on such industry intelligence as prospective companies, research, contacts, management strategy, applicable Cornell research, and approach tactics.

Form a Faculty Review Committee to approve Memos of Understanding and contracts and help guide post-agreement alliance management. The Trustee Research Subcommittee recommended a Local Advisory Committee of the Faculty Senate (LAC) serve as the internal faculty monitoring board and review all Strategic Alliance agreements before they are completed. (See Appendix B) With Weill Medical College participation, a member of the College's faculty would also serve on the Faculty Review Committee. In addition, academic deans would review proposed strategic partnerships.

Form a Negotiations Team to develop a Memorandum of Understanding and plan and carry out negotiations with prospective companies. They will be supported by the Office of Technological Licensing and Office of Sponsored Programs.

Strategic Corporate Alliance structure formation, implementation, negotiations, and post-agreement management, will be guided by existing Cornell University principles. (See Appendix C) in addition to Trustee Subcommittee Considerations and Principles.

Explain the Strategic Alliance concept to faculty groups beginning with those involved in the New Life Sciences. Conduct a series of meetings with academic deans.

II. Preparation

Apply the Cornell Corporate Strategic Alliance Planning Model (See Appendix D) and use Partners HealthCare's six-step process of "moving technology":

- Define goals;
- Understand own intellectual capital and research direction;
- Identify which companies should use the relevant technology;
- Understand the companies' relative strengths/ needs;
- Create a marketing plan (approach strategy);
- Communicate at the highest meaningful strategic level with a potential player.
 Work the system at the top. Bypass the corporate licensing office until the outlines of mutual interests are defined and agreed.

Aggressively search for opportunities through previous sponsored research, faculty-company connections, industry advisors, alumni, and secondary-research scans. Determine applications of Cornell research strengths.

Identify prospective companies (See Appendix E) for strategic alliances in five key bioscience-related industries, and other industry sectors:

- Ag Biotech (plant and animal)
- Bioengineering (devices, nano, biomed, biochips)
- · Food (human and animal) production, distribution, and safety
- Information (bioinformatics, database management)
- Pharmaceuticals

The list will remain dynamic as new information is sourced. Additionally, expand the alliance concept to other industries beyond the scope of the New Life Sciences where Cornell might apply its significant and growing strengths, e.g., computing and information, finance, training and education, etc.

Critically review Cornell bioscience/nanobiotechnology research to identify compelling work in each of the Focus Areas (See Appendix G) vis-à-vis prospective partner companies. Technologies, either as enabling or product, can be assessed on two attributes: breadth of technological application and degree of complexity. With regard to medicine, breadth is measured in terms of number of disease areas that it can be applied to; the greater number of applications the greater the commercial potential. Complexity is measured in terms of technical hurdles that must be overcome to generate a commercial product, and the cost of developing a particular technology.

Engage faculty representing NLS Focus Areas and Academic Deans in the Strategic Alliance initiative. Hold regular meetings with New Life Science Initiative faculty leadership. Seek faculty knowledge of company research interests, business strategies, and connections within prospective companies. Have Faculty Review Committee (i.e., LAC) guide formation of alliances and post-contract alliance management. Present proposed corporate strategic alliances to academic deans for discussion and review during Provost's Academic Deans Group meetings.

Develop communications materials including: a Power Point overview presentation of Cornell research capability, infrastructure, and culture; a flexible Power Point presentation that explains Focus Areas and faculty research within them, especially those relevant to a company's R&D and strategic business interests; a prospectus for each negotiation with assistance from the Office of Technology Licensing; and a brochure that explains the Cornell Strategic Corporate Alliances initiative.

III. Approach Strategy

Develop comprehensive profiles of prospective strategic alliance partners, including management and board of director personnel, business strategy, Cornell alumni, research and technology interests and needs, current academic /or business alliances, and research and development expenditures. Seek Cornell faculty knowledge of company's research interests and employees. Central to a company profile will be a "match-up" (See Appendix F) for side-by-side comparisons of a company's known or anticipated research/technology needs and related Cornell faculty research. The Offices of Sponsored Research and Technology Licensing will review "match-ups" to ascertain potential faculty research conflicts with current or pending commitments.

Develop an approach strategy (marketing plan) for each prospective partner that is based upon the company's business needs and culture; that considers Cornell connections (senior management, board memberships, key employees, alumni); that advances Cornell's most compelling research related to the company's need; and that assigns company contact at the highest meaningful level by senior Cornell administrators.

Identify the client. Determine who in the company, e.g., Senior Vice President – Research & Development, would be the recipient of Cornell's research.

Initiate exploratory meetings. Initiate meetings with company representatives through board members, senior management or appropriately placed staff, to learn the company's needs, technical and other interests, objectives and strategies. Provide an overview of Cornell's research capabilities, and discuss how an alliance would be in mutual best interest. Involve the Vice Provost for Research and/or faculty where applicable. If the parties conclude that discussions are warranted, a mutual non-disclosure agreement may be initiated.

Create for each company a Memorandum of Understanding (MOU) of key elements (see Appendix H) which will be approved by the Faculty Review Team (LAC) and relevant academic deans, and reviewed by Cornell Legal Counsel. The Cornell Team will develop a one-to-two page MOU conceptually -- what we want to do - and base its content on field of focus rather than personnel. The MOU identifies the expectations of the parties and source(s) of alliance funding. It is not legally binding, and it should have a "drop-dead" date. A legal review will be conducted. Following MOU approval by senior management, the company team will be expected to negotiate the contract to completion and establish the optimal structure and processes.

Assess market potential of Cornell research. Engage the Cornell Office of Technology Licensing and Economic Development to preliminary assess the market potential of Cornell research for early discussions.

Assist company scientists in evaluating Cornell research as they initiate due diligence that, among other things, will help strategic, operational, and cultural fit. A company team may visit faculty, hear presentations, and assess the research.

IV. Negotiation

The initial goal of the Cornell team is to obtain agreement of senior company officers on a Memorandum of Understanding specifying major terms of the transaction. The related, primary goal is to negotiate terms with either the same officers or functional and/or staff managers resulting in a contract. The team will be guided by federal guidelines and regulations, and Trustee and Cornell principles (*Appendix A, C*) during negotiations. The team will negotiate the scope of the research, other services, e.g., training, financial commitment, payment schedule, duration, alliance management structure, responsibilities, measurements, deliverables, and exclusivity.

The contract will have a "kick-out" clause if the company or Cornell fails to meet its commitments. The contract will also allow for flexibility if focus of research interest changes.

Cornell seeks from a Corporate Strategic Alliance:

- Financial commitment over a defined period of time for research and other services, e.g., training;
- Full overhead for research conducted within corporate alliance;
- A philanthropic portion for educational funding, e.g., fellowships, term professorships, building, laboratories, etc.;
- Opportunity to acquire materials for research;
- State-of-the-art equipment;
- Company interest in potentially licensing research;
- Opportunities for faculty and/or students to work in industry;
- Access to corporate partner's technology.

In addition, Cornell negotiators will consider applicable elements of PHS's strategy which seeks:

- Shared research (technology and results)
- Educational programs
- Access to corporate partner's technology
- Funding of graduate or post-doctoral fellows
- Funding of laboratories
- Supply of/funding for purchase of sophisticated equipment
- Management of each relationship by a joint steering committee

Among the benefits (see Appendix H, I) Cornell may offer companies are:

 A wide window into Cornell's New Life Science research with access to groups of researchers in Focus Areas of interest to the company;

- Opportunity to engage in multiple research projects beyond the scope of any one investigator;
- First look at discoveries;
- Opportunity to engage in internal faculty Requests for- Proposals;
- Research flexibility allowing for change in research direction as needs and interests change;
- A time-limited first option to negotiate a royalty-bearing exclusive license to resultant inventions or discoveries;
- Agreement that Cornell will not enter into research sponsored by competitors that involves the same investigator and similar work;
- Shared management of the Alliance via Joint Steering Committee;
- Facilitated access to facilities, faculty and students;
- Cornell will arrange opportunities for company employees' training.

The negotiations team will be comprised of the Vice Provost for Research, Vice Provost for Life Sciences, the Vice President, Alumni Affairs and Development, the Director of the Office of Technology Licensing and Economic Development, and the Director of the Office of Sponsored Programs. Cornell Legal Counsel, the Director of Corporate Relations, cognizant academic deans, and faculty participating in corporate strategic alliances, supports the team. Guidance and counsel is anticipated from the Industry Advisory Group and the Research Subcommittee of the Board of Trustees.

The Office of Technology Licensing and Economic Development will help establish the market potential of Cornell research by preparing a comprehensive prospectus for use during the negotiation process. This document makes the business case and includes select Cornell research projects (IP status, commercial positioning, competition, prospects for technology to displace technology, supporting data.) The Office of Technology Licensing and Economic Development and other support staff will critically review Cornell's position to determine strengths and weaknesses, fall-back positions, uncover gaps in available data, and anticipate likely questions. It will also present the argument of a Cornell University alliance versus an alliance with other higher-education institutions.

If the alliance is mutually satisfactory, Cornell may wish to continue for an additional period(s). However, termination provisions will be spelled out including who is entitled to terminate and why, whether the whole alliance ends necessarily, and the rights and duties of the parties upon termination.

V. Alliance Management

Successful alliances require leadership, compatible objectives, attention to the needs of both institutions, cultural mesh, good integration, flexibility, information exchange, and effective governance, in addition to leading-edge research. Cornell will determine who supplies what to whom initially and how and under what circumstances the arrangements can be changed. (See Appendix J)

- Clear determinations of decision-making will be made. A company-university Joint Steering Committee will be formed, led by a Cornell and company representative. The Vice Provost for Research will have overall responsibility for management of all alliances and will engage cognizant academic deans and center directors to help develop and maintain optimum relationships with Alliance company representatives. In Life Science alliances, the Vice Provost for Life Sciences will have working responsibility for managing alliances. Management responsibility may change, e.g., the Dean for Computing and Information Science may have overall responsibility for managing alliances in the computing and communications sectors.
- The Joint Steering Committee will review and select faculty proposals for funding.
- Faculty will have an opportunity to acquire materials for research.
- A new position of Director of Corporate Strategic Alliances will be created to assist the Vice Provost for Life Sciences, in Life Science alliances, by coordinating the faculty RFP proposal process, budgeting, reporting, and keeping companies fully engaged, e.g., facilitating symposia, arranging visits, and placing company researchers in residence at Cornell. He or she will look for opportunities to keep the alliance company involved, will maintain close communication and coordination with Cornell faculty, and will help bridge any culture gap by exhibiting and encouraging mutual trust and synergy among scientists.

VI. How Alliances Will Work Within Cornell

Cornell will receive from alliance companies annual funds for the duration of the agreement for faculty research and related philanthropic needs. Full overhead will be charged to corporate alliance companies. Agreements will include a philanthropic portion for educational funding, e.g., fellowships, term professorships, building, etc.

Faculty will receive RFPs and will apply for these funds by submitting proposals on a competitive basis to the Joint Steering Committee through the Director of Corporate Strategic Alliances. The Committee will meet and select proposals for funding but will not control or direct research or control faculty publishing. Regular faculty research reports will be required and interactions with company representatives encouraged. The company will receive the right of first refusal on any patents that might result from the work funded. The Office of Technology Licensing and Economic Development will patent discoveries and negotiate licensing.

VII. Licensing Discoveries

Licensing of Cornell intellectual property rights resulting from an Alliance will be conducted by the Office of Technology Licensing and Economic Development. License agreements will specify the terms and conditions under which a company may take actions that would otherwise infringe on Cornell's intellectual property rights. Principal terms will include the rights being licensed, where and for what purpose the rights may be exercised, and the consideration that the licensor will receive.

- CRF will evaluate the market potential of a discovery. It receives invention
 disclosure from the inventor and a CRF case manager will communicate
 information to the company sponsor or contact. The Company will be given 60-90
 days to review the discovery for possible licensing.
- If the company elects to license the invention or discovery, the CRF case manager will execute a limited confidentiality agreement (CDA) prior to exchanging proprietary information.
- License negotiation or option agreement granted (date established for license negotiation).
 - -- Exclusive license to inventions.
 - -- Non-exclusive license.
- License Agreement. Includes up-front fees, running royalties, diligence milestones, and minimum royalties.

Cornell should remain flexible and open to consideration of other forms of alliance arrangements and compensation including royalty-free alliances and assumption of equity positions in companies.

VIII. Institutional Memory

Capture and maintain a database of Alliance information to recycle into subsequent Alliance initiatives. The Director of Corporate Alliances will gather information, accessible by Cornell faculty and staff, on approach, negotiations, alliance management, relations management, and licensing processes, to build the university's institutional memory for improving subsequent strategic corporate alliance initiatives.

APPENDIX B

Trustee Document: Considerations & Principles Regarding Strategic Corporate Alliances (May 22, 2003)

Considerations and Principles Regarding Strategic Corporate Alliances

- I. The plan for Strategic Corporate Alliances for the Life Sciences, as developed, represents an enormous creative leap in Cornell's thinking about its educational and research mission and the role of outside enterprises. The Plan should serve as a prototype for the overall Cornell effort.
- II. The basis of any rationale behind the Plan for Strategic Alliances should be to create an effective and strong mechanism to further enable Cornell to execute and expand its research and educational missions.
 - 1. The academic independence of the University and the integrity of the Cornell name will be paramount.
 - 2. Research and academic considerations will be the primary factors in determining the goals, structures, operating procedures, and decision making related to corporate strategic alliances.
 - 3. The plan and participants recognize that external relationships, in all probability, will ultimately be governed by relationships at the researcher to researcher, scientist to scientist level.
 - 4. Faculty participation in any alliance, as outlined, will be voluntary.
 - 5. Participation by the highest-ranking members of the University's and the Faculty's administration is critical. Their commitment to the process and to the maintenance of specific relationships must be assured.
 - 6. The University should maintain a broad vision of what it seeks or may gain from any alliance. These elements may include, among others, research collaborations, laboratory or equipment access, provision of equipment, and/or funding of faculty, students, symposia, or facilities.
 - a. Maximizing licensing revenues and royalty income should not be the driving factor in structuring a general plan for strategic alliances.
 - 7. The University's intellectual property rights policies and the freedom of information principles in place at the time of the creation of a strategic alliance will serve as the guide for the alliance.

- a. A review of the University's intellectual property rights policies, considering the comments of the various panels in the Land Grant Mission Review, the Engineering Advisory Council, the Technology Transfer Committee of the University Council, the Cornell Research Foundation, and other University resources should be undertaken, optimally before any major strategic alliances are concluded.
- III. The active and ongoing participation and direction of President Rawlings, President Elect Lehman, and the Provost are requisite and crucial.
 - A. In addition to the colleges on the Ithaca campus, the Plan for Strategic Alliances should also include the Weill Cornell Medical College.
 - 1. Vice Provost / Dean Gotto and the Medical College should be involved in and committed to the planning, implementation, management, and execution of any alliance that touches upon the life sciences or human health care.
 - 2. Senior Weill Cornell personnel should be involved in reviewing all potential alliances that involve the life sciences or human health care. They will be a permanent part of the critical management and monitoring staff and management structure of all alliances involving the life sciences or human health care.
 - 3. Cooperation and collaboration between the Medical College and Ithaca should be understood to be essential in order to maximize the intellectual and economic benefits of relevant alliances.
- IV. The leadership of all other colleges, including Agriculture and Life Sciences, Architecture, Art, and Planning, Arts and Sciences, Engineering, Hotel, Human Ecology, Industrial and Labor Relations, Johnson Graduate School of Management, Law, and Veterinary Medicine, should be committed to the basic principles of the process embodied in the University's final plan, including the process of designing and implementing strategic alliances, as each may have something varied and valuable to contribute.
- V. Faculty should be deeply involved in the planning, execution, and monitoring of any plan for a specific strategic alliance, as well as being involved in and committed to the creation of the plan.
- VI. An independent External Monitoring and Advisory Board, with responsibility for monitoring whether the plan and alliances are operating in a manner consistent with the goal of furthering the University's research and educational missions, will be established. Such a panel will include faculty and administrators, as may be relevant, from peer institutions and will meet at least on an annual basis.

- VII. The *Local Advisory Committee of the Faculty Senate (LAC)* will serve as the internal faculty monitoring board and review all Strategic Alliance agreements before they are completed.
- VIII. A strong, effective, centralized management structure will be created at the appropriate time that is responsible for managing all components of any alliance.
 - 1. All opportunities for outside alliances should flow through this organization, although it will not have the ability to require involuntary participation.
 - 2. The organization should be a resource that allows the University to catalog and understand all potential components of a strategic alliance that may flow from the faculty or other intellectual or physical resources of the University.
 - 3. The organization should be the central contact point for parties wishing to collaborate with the University and should operate in a manner that makes the University and the organization easily accessible and responsive to faculty and potential or existing corporate partners.
 - 4. Research and academic considerations should be the primary determinants of any management decisions.
 - 5. The organization should be flexible in structuring any strategic alliance, understanding that differing scientific fields, academic / research endeavors, and corporate enterprises have differing strengths and needs. These should be accommodated to provide benefits to all parties.
 - 6. The organization will report to a high-level executive of the University.
- IX. The plan, and any alliances, will include provisions that will require periodic review and would allow the University to implement modifications or terminate alliances that were not judged to be successfully furthering Cornell's research or educational missions.

APPENDIX C

Current Cornell Principles to Guide Development of Strategic Corporate Alliances (undated)

Current Cornell Principles to Guide Development of Strategic Corporate Alliances

- 1. The involvement of Cornell researchers in corporate alliances will be voluntary and will not disrupt existing relationships they have with other sponsors of their research, including corporate sponsors who do not enter into broad research alliances with Cornell.
- 2. Corporate research sponsorships will be reviewed with relevant federal funding agencies to ensure that the agreements avoid federal concerns regarding corporate sponsors inappropriately leveraging their support against federal grants, and circumventing the intent of the Bayh-Dole Act.
- 3. Cornell researchers will retain the ability to publish the results of research conducted under the relationship. Reasonable delays would be permitted for review for confidential company information, patentable subject matter, and, if appropriate, preparation of patent applications. In no case will the total delay exceed 90 days
- 4. Cornell will own all patents made by its faculty, post-docs, students and staff, and will license these inventions for commercial development for the public good in a manner consistent with Cornell University Patent Policy. This will include no paid up licenses, diligence requirements, and the ability to terminate the license for failure to perform.
- 5. Cornell will retain the right to practice any inventions for its own research and education purposes, and will retain the ability to distribute any biological materials created under a corporate research sponsorship to other academic researchers.

APPENDIX D BIBLIOGRAPHY

Items marked with (*) are available http://web.cornell.edu/UniversityFaculty/

- 1. Bekelman JE, Li Y, Gross CP. Scope and impact of financial conflicts of interest in biomedical research: a systematic review. JAMA 2003;289:454-65.
- 2. Robert M. Berdahl, Chancellor, U. Cal. Berkeley, The Privatization of Public Universities, May 23, 2000, available at http://cio.chance.berkeley.edu/chancellor/sp/privatization.htm.
- 3. David Blumenthal, Academic-Industrial Relationships in the Life Sciences, NEJM 2003; 349;25: 2452-2459.
- 4. Derek Bok, Universities in the Marketplace: The Commercialization of Higher Education, Harvard University Press, 2003.
- * 5. David Bollier, Sr. Fellow Norman Lear Center, Preserving the Academic Commons, Keynote Address, AAUP Annual Meeting, June 13, 2003.
- 6. Martin Kenney, Biotechnology: The University-Industrial Complex (1986).
- 7. Sheldon Krimsky, Science in the Private Interest (2003).
- 8. Sheldon Krimsky, The Profit of Scientific Discovery and Its Normative Implications, 75 Chi.-Kent L. Rev. 15 (1999).
- * 9. David C. Montgomery, A Kelvin Smith Professor of Physics, Dartmouth College, Marketing Science, Marketing Ourselves. Academe, Sept/Oct 2003.
- 10. Eyal Press and Jennifer Washburn, The Kept University, The Atlantic Monthly, March 2000.
- * 11. Robert Rosenzweig, President Emeritus, Amer. Assoc. Universities, What's For Sale These Days in Higher Education? U.Cal. Berkley Center For Studies in Higher Ed, Oct. 26, 1999.

[A more extensive bibliography on biomedical research is available on request from crf7@cornell.edu.]

LITERATURE RELATING SPECIFICALLY TO NOVATIS SPONSORSHIP AT BERKELEY

- 1. Busch, et al, External Review of the Collaborative Research Agreement Between Novartis Agricultural Institute Inc and the Regents of the University of California at 154 (July 31, 2004) [hereinafter "External Review", available at http://www.berkeley.edu/news/media/releases/2004/07/external_novartis_review.pdf]
- * 2. Berkeley teams up with Novartis in \$50m plant genomics deal. Nature, 05 Nov 1998.
- * 3. Editorial: "Is the university-industrial complex out of control? Nature, 11 Jan 2001.
- * 4. Response (29 Mar 2001) [with link to text of Berkeley-Novartis agreement].
- * 5. Vilified Corporate Partnership Produces Little Change (Except Better Facilities). The Chronicle of Higher Education, Jun 22, 2001.
- * 6. Corporate Cash and Campus Labs. Christian Sci Mon, 19 June 2001.
- * 7. Novartis Revisited. Pro: Bob Buchanan / Con: Dr. Ignacio Chapela. California Monthly Feb. 2002.
- * 8. Closing the Book on the Novartis Deal. Berkeleyan 29 Jan. 2003.