

APPENDIX P: POLICIES RELATED TO RESEARCH

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Protecting Human Subjects in Nonmedical Research

Duke has an agreement with the Office for Human Research Protections (OHRP) and a supplementary Duke Policy.

In the agreement with OHRP, Duke does three things:

I. **Adopts a set of ethical principles: "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research."**

II. **Agrees to abide by regulations for the protection of human subjects: Title 45 Code of Federal Regulations Part 46 (45 CFR 46).**

III. **States that these ethical principles and regulations apply to all research with human subjects, regardless of the funding source.**

The Duke Policy, "Duke University Principles and Procedures Regarding Research on Human Subjects (Campus)," approved by the Academic Council on September 21, 2000, includes a statement of principles and provides additional protections for students and Duke employees in order to avoid the potential for coercion, however unintended, of those subjects.

Summaries of The Belmont Report and 45 CFR 46, and links to the full texts of each, are available at the following URLs:

- The Belmont Report: <http://www.ors.duke.edu/irb/regpolicy/ethical.html>
- 45 CFR 46: <http://www.ors.duke.edu/irb/regpolicy/federal.html>

Investigators must be certified to conduct research with human subjects. For information on the certification process consult <<http://www.ors.duke.edu/irb/fundamentals/certification.html>>.

A Very Abbreviated Summary of "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research"

Report Prepared By: The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

When: September 30, 1978

Purpose: Respond to a congressional charge to set forth the basic ethical principles underlying the acceptable conduct of research involving human subjects. Those principles, respect for persons, beneficence, and justice, are now accepted as the three fundamental requirements for the ethical conduct of research involving human subjects.

Summary: Respect for persons involves recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. Respect for persons requires that investigators secure fully informed and voluntary consent from subjects. Presentation of information must be adapted to subject's capacity to understand it (language, language level) and culturally appropriate.

The principle of beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. Finally, justice requires that the benefits and burdens of research be distributed fairly. Justice of subject selection relates to subjects as individuals and as members of social, racial, sexual, or ethnic groups.

***A Brief Summary of Title 45 of the Code of Federal Regulations,
Part 46, Protection of Human Subjects***

The basic components of the code are:

- I. **Activities covered by the code.** This section includes:
 - A. A list of research activities that may be screened for exemption by administrative staff. (Duke requires that IRB Administrators make determinations of exemption, rather than investigators.)
 - B. Notice that state, local, and foreign laws may provide additional protections.
 - C. Notice that if the research takes place in foreign countries, the protections of that country, if at least equivalent to this code, may be substituted.

- II. **Definitions of terms** such as *research, human subject, private information, intervention*, and so on. This section is critical because it provides the tools for identifying when research constitutes research with human subjects.

- III. **Assuring Compliance with 45 CFR 46.** Institutions must have a written assurance on file with the Office for Human Research Protections. The format this agreement takes is dictated by OHRP. It must, however, include:
 - A. A statement of ethical principles adopted by the institution that covers all research with human subjects, whether or not it is subject to federal regulation. Duke has adopted the Belmont Report.
 - B. Designation of an IRB established in accordance with the code, with meeting space and sufficient staff.
 - C. A list of IRB members.

- IV. **IRB Membership Criteria**
 - A. Number of members
 - B. Expertise
 - C. Diversity
 - D. Conflict of interest

- V. **IRB Functions**
 - A. Make decision by simple majority of quorum.
 - B. Approve, require modifications to, or disapprove all research activities covered by the assurance.
 - C. Require informed consent.
 - D. Require documentation of consent or waive documentation in accordance with code.
 - E. Notify investigators in writing of its decisions.
 - F. Conduct continuing review at intervals appropriate to the degree of risk, but no less frequently than twelve months.
 - G. If needed, observe, or have a third party observe the consent process and the research.

- VI. **Expedited Review Procedures**
 - A. A list of categories that may be reviewed through expedited procedures is published in the federal register.
 - B. An IRB may also use expedited review for minor changes to approved research.
 - C. Review may be carried out by one or more experienced members or the Chair.
 - D. Review criteria are the same as for full review. (See next section.)
 - E. An expedited reviewer may not disapprove a protocol.
 - F. All members must be advised of expedited approvals with the option to request consideration by the full IRB.

- VII. **Criteria for Approval of Research**

Seven basic requirements must be met:

 - A. Risk to subjects must be minimized.
 - B. Risks must be reasonable in relation to anticipated benefits.
 - C. Selection of subjects must be equitable.
 - D. Informed consent must be sought.
 - E. Informed consent must be appropriately documented.
 - F. Adequate provisions are in place to protect the privacy of subjects and maintain the confidentiality of data.

- G. When appropriate, provisions must be made for data monitoring to ensure the safety of subjects. (Rarely applies to social and behavioral science research.)

VIII. **Review by Institution.** The institution cannot approve research not approved by the IRB. Institutional officials can subject research to further review and possible disapproval.

IX. **IRB Authority to Suspend or Terminate Approved Research.** Authorized when research is not being conducted in accordance with IRB requirements, or when there is unanticipated serious harm to subjects.

X. **Cooperative Research.** Describes available mechanisms for review of projects involving more than one institution.

XI. **IRB Records.** A list of documents that must be kept by the IRB administrative offices for three years after the administration of the project. Investigators are subject to Duke's data retention policy.

XII. **General Requirements for Informed Consent.** In addition to the list of required elements of consent, this section lists some components of the consent process, such as:

- A. It shall be sought under circumstances which allow the prospective subject enough time to consider whether or not to participate, and which minimize the possibility of coercion or undue influence.
- B. The information shall be given in a language understandable to the subjects.
- C. No informed consent whether oral or written, may include language in which subjects waive or appear to waive their legal rights.

This section also includes a description of the circumstances under which an IRB may waive some or all of the elements of consent.

- D. The research involves no more than minimal risk to subject, and
- E. The waiver or alteration will not adversely effect the rights and welfare of the subjects, and
- F. The research could not practicably be carried out without the waiver or alteration, and
- G. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

XIII. **Documentation of Informed Consent.** Describes two conditions under which the IRB may waive the requirement for the investigator to obtain signed consent forms from the subjects. (This does not mean that the subject does not get a written statement regarding the research.)

- A. The only record linking the subject to the research is the consent form and the greatest risk is a breach of confidentiality.
- B. The research involves no procedures for which written consent is normally required outside the research context and there is no more than minimal risk. Some survey research falls in this category.

XIV. **Miscellaneous.** The final sections of the code discuss issues such as the procedures to be followed if a researcher didn't plan to use human subjects, but later proposes to do so, and federal sponsors' authority to evaluate protocols and the institution's performance.

Duke University Principles and Procedures Regarding Research on Human Subjects (Campus)
Approved by Academic Council September 21, 2000

I. Scope of the Policy

- A. These principles and procedures are adopted by the Academic Council (the academic senate of Duke University) to govern the conduct and review of all research involving human subjects conducted by Duke University researchers outside of the Medical Center.

II. Principles

- A. Duke University is committed to academic freedom. Research will neither be forbidden nor discouraged because it explores topics that are innovative, unorthodox, sensitive, unusual, or otherwise extraordinary. The university takes responsibility for protecting the right of the faculty to conduct research in the pursuit of knowledge, wherever that search may lead.
- B. In the conduct of research, care must be taken to avoid harming the persons being studied. Research procedures should minimize the risk of harm and respect the privacy of subjects. The researcher should not withhold from the subjects information they request about any aspect of the research likely to be significant to the subject or induce subjects to participate by means that might affect the subject's ability to decide freely about his or her participation. Researchers who promise confidentiality are responsible for maintaining it and for informing subjects of limits on their capacity to meet that responsibility. Researchers should explain to subjects, prior to their participation, the purposes of the research. Special care is called for when the subjects of the research are especially vulnerable to harm because they cannot understand the risks or because they are not in a position to freely refuse their participation in the research.
- C. To resolve any conflict between the above principles, and to assure that research at Duke University follows these principles, the following procedures should be followed.
- D. In developing these procedures, the university has considered the ethical codes of all the principal scholarly associations.

III. Procedures

- A. The Institutional Review Board for Protection of Human Subjects in Non-Medical Research (IRB) will satisfy the compositional requirements for membership described in federal regulations. The IRB will have sufficient membership to represent the primary disciplines conducting non-medical research with human subjects at Duke, with no fewer than nine members. The Executive Committee of the Academic Council will appoint faculty members. The Provost will appoint non-faculty members. The ordinary term of service is three years.
- B. The Office of Research Support will provide administrative and logistical support for the activities of the IRB. Staff of the Office of Research Support will also provide continuing training for the IRB and investigators.
- C. The review procedures and criteria set forth in the University's current Multiple Project Assurance (MPA)* will govern all human subject research conducted under the auspices of the University, outside the Medical Center, regardless of sponsorship.
- D. The committee will review submitted research plans and approve, disapprove, or state conditions for the conduct of the research, applying the principles and procedures specified in this resolution and in applicable federal regulations. Other criteria, such as the scientific or social value of the research or the adequacy of the research methods to research goals, are applied elsewhere in the university and are not the charge of the IRB.
- E. To assure that extra care is taken in research involving special researcher-subject relationships within the university, several types of research will be submitted to the full committee for review:
 - 1. Research conducted on employees of the University by their supervisors.
 - 2. Research conducted by faculty or instructors on students in their classes.
- F. Research conducted on subjects whose participation in the Psychology subject pool is a requirement for course credit may not be screened for exemption from review, even if there is no more than minimal risk to the students, but will be subject to "expedited" or "full committee" review, as these terms are used in the Federal Policy for the Protection of Human Subjects.

- G. It is the responsibility of faculty members to supervise student research in their courses and departments in accordance with all applicable regulations and to refer students to the IRB when appropriate.
- H. These principles and procedures may be amended by vote of the Academic Council.

IV. Procedures for Proposals Requiring Review

- A. The IRB will meet twice a month from September through April and at least once per month during the remaining months. The schedule of meeting dates and submission deadlines will be posted on the human subjects web site, maintained by the Office of Research Support. Ad hoc meetings may be held at the discretion of the chair.
- B. Procedures for the submission of materials for review, and additional administrative guidelines, are provided on the human subjects web site.
- C. Basic review, as described in Duke's MPA*, will ask the following questions:
 - 1. Have the risks to subjects been minimized?
 - 2. Are the risks reasonable in relation to anticipated benefits?
 - 3. Is the selection of subjects equitable?
 - 4. Are adequate procedures in place to ensure privacy and confidentiality?
 - 5. Has informed consent been sought and appropriately documented?
 - 6. Are safeguards in place to protect vulnerable populations?
 - 7. If the research is federally funded, is the protocol consistent with the grant application?
- D. IRB actions will be promptly communicated to investigators in writing.
- E. Copies of all protocol materials will be maintained at the Office of Research Support.

* The Multiple Project Assurance was replaced by a Federal-wide Assurance in March of 2001. The assurance process has been streamlined and the resulting documents given a new name.

Policy on Inventions, Patents, and Technology Transfer

I. Preamble and Objectives

Duke University is dedicated to teaching, research, and the expansion of knowledge. Although the university does not undertake research or developmental work principally for the purpose of developing patents and commercial applications, patentable inventions sometimes result from the research activities carried out wholly or in part with university funds and facilities. It is the policy of the university to assure the utilization of such inventions for the common good and, where necessary, to pursue patents and licenses to encourage their development and marketing.

This policy applies to university employees who are defined for purposes of this policy as all faculty, staff, and other persons receiving compensation from the university for services rendered, as well as students and graduate assistants, whether compensated or not, who work on any research project under university control.

Duke University has established the following policies and procedures with respect to inventions, patents, and technology transfer in order to:

- A. Promote the university's academic policy of encouraging scientific research and scholarship;
- B. Serve the public interest by providing an organizational structure and procedures through which inventions which arise in the course of university research may be made readily available to the public through established channels of commerce;
- C. Encourage, assist, and provide tangible reward to members of the university community who make inventions processed under this policy.
- D. Establish principles and uniform procedures for determining the rights and obligations of the university, inventors, and sponsors, with respect to inventions arising during the inventor's and sponsor's association with the university;
- E. Enable the university to enter into institutional agreements with federal research funding agencies;
- F. Produce funds for further scientific investigation and research and for the overall needs of the university.

II. Administrative Responsibility

- A. The president of the university shall be responsible for administrative matters relating to inventions, patents, and technology transfer and shall represent the university in all matters of policy affecting the university's relations with inventors, government, private research sponsors, industry, and the public. The president may designate another senior administrative officer to carry out these responsibilities in whole or in part.
- B. Director of the Office of Corporate and Venture Development. The president of the university shall appoint a director of the Office of Corporate and Venture Development who may be a full or part-time employee of the university or a recognized patent management organization. The director of the Office of Corporate and Venture Development shall:
 1. Establish liaison with appropriate faculties to monitor research and to assist in the identification of potentially patentable discoveries and in the reporting of such discoveries;
 2. Establish liaison with federal and private sponsors of research and ensure compliance with any provisions in sponsored research agreements regarding inventions;
 3. Receive all disclosures of invention submitted under this policy;
 4. Determine the ownership of and equities involved in inventions, in accordance with Section V below;
 5. Determine whether an invention in which the university has an equity is patentable;
 6. In consultation with the inventor, evaluate potential commercial use and investigate possible courses of action for patenting and/or marketing inventions in which the university has an equity;
 7. Negotiate patent licensing and technology transfer agreements;
 8. Maintain complete records on all disclosures and other patent matters of interest to the Duke administration;
 9. Serve as an ex-officio member of the University Patent Policy Committee in the capacity of secretary, and prepare an annual report to the committee;
 10. Promote the cross-fertilization of ideas within the Duke scientific community consistent with the need for confidentiality of potentially patentable subject matter until patent applications have been filed.

- C. University Patent Policy Committee. The president of the university shall appoint a University Patent Policy Committee consisting of five members. Three committee members shall be selected from the faculty and two from the administration. One faculty member shall be selected from the School of Medicine and one from the Pratt School of Engineering. The chairman shall be designated by the president of the university. The committee shall:
 - 1. Receive and review the annual report of the director of the Office of Corporate and Venture Development and consult with the director of the Office of Corporate and Venture Development when requested.
 - 2. Report to the president on the implementation of this policy, and recommend such new or different policies or guidelines as may be more suitable for the achievement of its objectives.
 - 3. Sit as a tribunal for the resolution of specific disputes involving the ownership of and equities involved in inventions, on appeal from decisions of the director of the Office of Corporate and Venture Development.
 - 4. Receive requests for interpretations of this policy and, after deliberation, recommend to the president such interpretations as it considers appropriate.

III. Invention Management

- A. For all inventions assigned to the university under this policy, the university will at no expense to the inventor make reasonable efforts to evaluate the interest to others in commercializing the invention, seek licenses and options for licenses, have applications for patents filed and prosecuted, and otherwise manage the inventions or arrange for their management by recognized patent management organizations. The university may assign such inventions to a foundation or corporation organized by the university for purpose of patent management.
- B. The university will normally evaluate potential commercial use of an invention prior to the filing of patent application. Options to license and other contractual arrangements appropriate in the circumstances will normally be sought as early as possible as a validation of potential commercial use. If the university determines that neither commercial possibilities nor the potential contribution to the public good warrants proceeding further, the invention will be returned to the inventor and shall belong to him unless such action is precluded by prior agreement with sponsors. The university shall make such determination within a reasonable time, in no event longer than one year from the date of disclosure.
- C. In licensing, sale, or other disposition of rights to inventions, the university will seek to guard against repressive practices. Royalty rates shall be reasonable and consistent with the goal of the university effectively to transfer technology in the public interest. Where feasible, the university will grant non-exclusive, reasonable royalty-bearing licenses to all qualified licensees. However, the university recognizes that non-exclusive licensing in many cases may not be effective in bringing the invention to the commercial market in a satisfactory manner and thus will grant an exclusive license if it determines that such is required in the public interest to encourage the marketing and eventual public use of the invention. In all cases, the university shall reserve to itself a right to make or have made and to use the invention within Duke University for its own purposes.
- D. If within a reasonable time from the date of issuance of the patent the university does not license or sell a patent assigned to it, ownership of the patent will revert to the inventor at his/her request.

IV. Report of Inventions

University employees who during their associations with the university invent a device, product, or method, whether or not on university time or with university facilities, shall cooperate with the university in defining the rights to such inventions by promptly reporting to the director of the Office of Corporate and Venture Development on the university's Invention Disclosure Form.

V. Ownership of Inventions and Supportive Technology

- A. Inventions resulting from research or other work conducted by university employees wholly on their own time and without use of university funds or facilities shall be considered the property of the inventor and may be patented and/or commercialized by the individual at the individual's expense. It is recognized that when the invention is within the specific subject area of the inventor's current and ongoing university research activities, disputes may develop concerning whether the work was conducted by university employees wholly on their own time and without use of university funds or facilities. In order to reduce the

possibility of such disputes, it shall be the responsibility of the employee to provide his or her departmental chairman notice that he is engaging in research activities independently within the subject area of his current university research, and describe in such notice the focus of these independent research activities, with a copy to the provost or chancellor for health affairs. In questionable cases, it shall be the responsibility of the inventor to demonstrate that the above criteria are present.

- B. Inventions resulting from research or other work conducted by university employees wholly on their own time, but involving some but not significant use of the university funds or facilities, shall be considered the property of the individual and may be patented and/or commercialized by the individual at the individual's expense. The university will not construe the payment of salary from unrestricted funds or the provision of office or library facilities as constituting significant use of university funds or facilities. However, a percentage of gross returns to the inventor shall be remitted, in recognition of the use of university facilities, to the university, as provided hereafter.
- C. Inventions resulting from research or other work conducted by university employees in whole or in part on university time or with significant use of university funds or facilities shall be considered the property of the university. Employees shall upon request assign to the university all rights and title to such inventions and shall make known and available to the university all supportive technology related to the same. Supportive technology is intended to include any non-patentable invention which would assist the university in achieving the goals of this policy. If the university decides not to request assignment of all rights and title to such an invention, and if there are no restrictions by any outside sponsor of the research, the university may release its proprietary interest to the inventor.
- D. Inventions arising from research financed by the U.S. Government are controlled by the terms of the applicable grant or contract. The university is obligated to report to the appropriate government agency all such inventions or discoveries for definition of the government's rights and interests. In cases where the government claims no patent rights or waives its rights, university patent policies will control, subject to such limitations as the government may impose.
- E. Inventions resulting from research or other work sponsored by nongovernmental entities are controlled by the terms of the research agreement, if applicable, and if not, by university patent policies.
- F. Where mutually agreeable between inventors and the university, and on terms and conditions acceptable to both, the university will accept by assignment, bequest, or other appropriate instrument, title to inventions falling in sections A and B above.
- G. Any dispute between the director of the Office of Corporate and Venture Development and the inventor as to the determination of equities in an invention shall be resolved by the University Patent Policy Committee. The decision of the University Patent Policy Committee may be further appealed to the president or, upon the president's referral, to the Board of Trustees.
- H. Any use of the university's name in connection with the commercialization of an invention by an individual shall be approved in advance by the university.

VI. Division of Income

- A. All income derived from inventions falling within Article V, section A above shall belong to the inventor.
- B. All inventions falling with Article V, section B shall be patented and/or commercialized, if at all, under a simple agreement between the university and inventor which shall provide for periodic reports of sales subject to royalties and for payment to the university of ten percent (10%) of gross income derived by the inventor as royalties on the invention. The president and senior officers may decide that such payment be reduced or eliminated if it appears that a 10% contribution is excessive under the circumstances.
- C. All income derived from inventions falling within Article V, section C shall be distributed in accordance with the following rules:
 - 1. The university will first deduct any direct expenses incurred by it in connection with the initial patenting and commercialization of the invention. Any such expenses incurred by the inventor with the prior approval of the director of the Office of Corporate and Venture Development will also be deducted and paid to the inventor.
 - 2. The university will then pay and distribute the income remaining after payment of direct expenses in the following manner:
 - a. income from \$0 to \$500,000:
 - (1) fifty percent (50 %) thereof to the inventor;
 - (2) ten percent (10 %) thereof to the Office of Corporate and Venture Development;

- (3) ten percent (10 %) thereof to the inventor's laboratory until, in the discretion of the president after consultation with the chancellor of health affairs or the provost, this distribution equals the maximum amount which can reasonably be expended in that laboratory, after which any excess shall be added to and distributed as a part of the twenty percent (20%) share to be distributed for research support in accordance with VI.C.2.a.(5) below;
 - (4) ten percent (10 %) thereof to the inventor's department; and
 - (5) twenty percent (20 %) thereof to provide research support in the university as determined by the president upon the advice and counsel of the chancellor for health affairs or the provost.
- b. income from \$500,000 to \$2,000,000:
 - (1) thirty-three percent (33 %) thereof to the inventor;
 - (2) ten percent (10 %) thereof to the Office of Corporate and Venture Development;
 - (3) fifteen percent (15 %) thereof to the inventor's laboratory until, in the discretion of the president after consultation with the chancellor of health affairs or the provost, this distribution equals the maximum amount which can reasonably be expended in that laboratory, after which any excess shall be added to and distributed as a part of the twenty percent (20%) share to be distributed for research support in accordance with VI.C.2.b.(6) below;
 - (4) fifteen percent (15 %) thereof to the inventor's department;
 - (5) seven percent (7 %) thereof to the inventor's school; and
 - (6) twenty percent (20 %) thereof to provide research support in the university as determined by the president upon the advice and counsel of the chancellor for health affairs or the provost.
 - c. \$2,000,000 and higher:
 - (1) twenty-five percent (25 %) thereof to the inventor;
 - (2) ten percent (10 %) thereof to the Office of Corporate and Venture Development;
 - (3) fifteen percent (15 %) thereof to the inventor's laboratory until, in the discretion of the president after consultation with the chancellor of health affairs or the provost, this distribution equals the maximum amount which can reasonably be expended in that laboratory, after which any excess shall be added to and distributed as a part of the twenty percent (20%) share to be distributed for research support in accordance with VI.C.2.c.(7) below;
 - (4) fifteen percent (15 %) thereof to the inventor's department;
 - (5) five percent (5 %) thereof to the inventor's school;
 - (6) ten percent (10 %) thereof to a quasi-endowment fund established by the university to provide direct support for graduate and post-doctoral research, as the president of the university shall direct; and
 - (7) twenty percent (20 %) thereof to provide research support in the university as determined by the president upon the advice and counsel of the chancellor for health affairs or the provost.
3.
 - a. If for any reason the inventor ceases to be a university employee or, if not an employee is no longer studying or working in research at the university, then the disposition of the share to which that inventor's laboratory would have been entitled shall be determined by the school.
 - b. For purposes of this Article VI.C., the word "inventor" shall include co-inventors as a group and related words such as "laboratory" shall include not only the singular but also the plural form of the word, as may be appropriate.
 - c. For purposes of this Article VI.C., the dollar ranges in paragraphs VI.C.2.a. (0 to \$500,000), VI.C.2.b. (\$500,000 to \$2,000,000), and VI.C.2.c. (\$2,000,000 and higher) above, shall be adjusted by the director of the Office of Corporate and Venture Development as of July 1 of each year to reflect the change, if any, in the cost-of-living, such adjustment to be effective for the fiscal year from that July 1 through the following June 30. The cost-of-living adjustment to be made each year shall be the cost-of-living adjustment calculated by the Department of Human Resources of the university for use by that department in determining wage and salary levels for the fiscal year for which the adjustment of dollar ranges under this Article VI.C. will be effective (whether or not such wage and salary adjustments are implemented). In any year in which the Department of Human Resources of the university does not make such a calculation, then the director of the Office of Corporate and Venture Development shall obtain the same cost-of-living calculation

from the Department of Human Resources which that department would have made for determining wage and salary levels if that calculation had been required by that department, for the purpose of making the adjustments required by this Article VI.C.3.c. The adjustments shall be published as amendments to this policy no later than July 1 of each year in which such amendments are effective.

- d. For purposes of this Article VI.C., the net income referred to in paragraphs VI.C.2.a. (0 to \$500,000), VI.C.2.b. (\$500,000 to \$2,000,000), and VI.C.2.b. (\$2,000,000 and higher) above, as the same shall be adjusted from time to time, shall mean the cumulative net income earned from inventions.
- D. Income from inventions falling within Article V, section D, where the government claims no patent rights or waives such rights, shall be distributed in accordance with Article VI, section C above, unless the waiver or other agreement between the university and the government provides for a different distribution.
- E. In the case of inventions falling within Article V, section E, any royalties received by the university shall be distributed in accordance with Article VI, section C above, unless the contract between the university and the sponsor provides for a different distribution.
- F. Income from inventions falling within Article V, section F, shall be distributed in accordance with the agreement between the inventor and the university.

VII. Publication

Inventors should be aware that publication prior to the filing of a U.S. patent application is a bar to the grant of certain foreign patents and can bar the grant of a U.S. patent if it occurred a year earlier than the filing date.

VIII. Interpretation

Questions of interpretation concerning this policy shall be submitted to the University Patent Policy Committee and resolved, after consideration of the University Patent Policy Committee's recommendations, by the president or, upon the president's referral, by the Board of Trustees.

IX. Termination or Revision of Policy

This policy may be changed or discontinued at any time by action of the Board of Trustees. Such changes or discontinuance shall not affect rights accrued prior to the date of such action.

X. Agreements

The policy as amended from time to time shall be deemed to be a condition of initial or continuing employment of every university employee and a condition of enrollment and attendance of every student who works on any research project under university control. All such employees and students will be expected to sign agreements incorporating the terms of this policy; but failure to sign shall not affect the applicability of the policy nor relieve any employee or student from the obligations imposed by it. Any use of university funds or facilities after the effective date of this policy shall be subject to this policy.

XI. Effective Date

This revision of the policy on Inventions, Patents, and Technology Transfer shall be effective July 1, 1996.

Interpretations of the Policy on Inventions, Patents, and Technology Transfer

The university agrees to the following interpretations of its policy on Inventions, Patents, and Technology Transfer.

- **Article III-A.**

The university has created an Office of Corporate and Venture Development to manage all inventions assigned to it under this policy, and does not anticipate assigning any such inventions to an existing patent management organization such as Research Corporation. In the unlikely event the university decides to use such an organization for patent management, the inventor's agreement would be obtained in advance.

- **Article IV.**

To avoid the possibility of adverse impact on faculty members' private consulting arrangements, the university intends to amend its disclosure form to first request information concerning the basic idea of the invention (what it will do but not how it does it) and the circumstances of its conception and/or development (whether on university time or not, what funding sources were involved, etc.). If the director of the Office of Corporate and Venture Development concurs with the inventor that the invention is not one in which the university has equity under the patent policy, the remainder of the disclosure form need not be completed.

- **Article VII.**

Inasmuch as a publication prior to the filing of a U.S. patent application is a bar to the grant of certain foreign patents and can bar the grant of a U.S. patent if it occurred a year earlier than the filing date, it may be necessary in some circumstances to temporarily restrict publication for short periods of time. Accordingly, the university may request employees to delay the publication date of any publication which discloses an invention made within the scope of their duties to the university until after a U.S. patent application has been filed on the invention, but in no event longer than three months.

Duke University Policy on Intellectual Property Rights

Approved May 11, 2000. To be effective July 15, 2000.

I. General Principles

- A. Duke's primary mission lies in the creation and dissemination of knowledge in works of the intellect, in whatever medium (tangible or otherwise) they may be embodied or expressed. This Policy recognizes and acknowledges that intellectual property rights (other than patent rights) may arise in such works from time to time as a result of efforts by members of the Duke community. The Policy addresses certain recurring issues of ownership with respect to such rights. In this Policy Duke reaffirms its traditional commitment to the personal ownership of intellectual property rights in works of the intellect by their individual creators, whether the creators work alone or with others, and whether they work privately or as members of the Duke community, defined for purposes of this policy as all faculty, staff, and other persons receiving compensation from the university for services rendered, as well as students and graduate assistants, whether compensated or not, who work on any research project under university control.
- B. As in the past, Duke also may create or commission such works in its own behalf, whether as works-for-hire or otherwise; and Duke may acquire such works from, or develop them in company with, individual authors on mutually agreeable terms.
- C. Throughout this Policy, the term "intellectual property rights" includes, inter alia, copyrights, trademarks and unfair competition, trade secrets, rights of publicity or privacy, the law of ideas, moral rights, and all other neighboring rights of whatsoever kind; but the term excludes patent rights arising in inventions of the sort addressed in the University's Policy on Inventions, Patents and Technology Transfer, effective July 1, 1996. Know-how associated with patentable inventions or tangible material is not included in this policy.

II. Recurring or Categorical Exceptions

- A. Notwithstanding the general principles respecting individual ownership expressed in Article I, intellectual property rights arising in certain categories of academic works (i.e., works primarily related to the teaching or research missions of the university), appear to justify exceptional treatment on a recurring or categorical basis:
 - 1. Computer programs, when the programs are primarily created to perform utilitarian tasks.
 - 2. Data bases and similar collections of information which are obtained primarily on behalf of schools or departments rather than individuals, or which involve issues of privacy (as in the case of medical patients or identifiable human subjects) or require approval by the University's Institutional Review Board.
 - 3. Works supported by extraordinary allowances, grants or subventions (whether in money or money's worth, and whether or not supported by outside sources under contract), when designated as such in advance by the University. Works obviously created in such circumstances prior to the date of this Policy shall be deemed covered by this Policy without requiring that prior designation have been given.
 - 4. Collaborative works by persons working as members of the Duke community, when numerous individual original contributions are indistinctly merged, as a practical matter, into a new and distinct work fixed in a tangible medium of embodiment, and the individual creators have not entered into an agreement with respect to joint authorship.
 - 5. Intellectual property rights in works supported by grants or contracts shall be governed according to the terms and conditions of such grants or contracts or, in the event such grants or contracts are silent as to intellectual property rights, such grants or contracts shall be governed by this policy.
- B. In each instance, the intellectual property rights arising from the creation of these works shall vest (as works for hire or the equivalent) in Duke, which may thereafter grant licenses or royalties or both to individual creators or contributors on just and reasonable terms.

III. Particular Provisions Applicable to Courses of Instruction Approved for Duke Credit

- A. Intellectual property rights arising in courses approved for Duke University credit ordinarily belong to their individual creators in accordance with the general principles expressed in Article I of this Policy; but rights may vest in Duke to the extent that a course (or some portion of it) is created, acquired or developed by Duke under Article I, or when the course (or some portion of it) falls within the exceptions set forth in Article II.
- B. With respect to each such course (and whether the rights in that course belong to an individual creator or to Duke), every member of the university community at large (including students, faculty, staff and administrators) shall enjoy a permanent non-exclusive, royalty free license to make all traditional, customary or reasonable academic uses of the immediate content of that course (the License).

- 1. The "immediate content" of a course includes both the ideas and the expression arising *ex tempore* as the course is actually taught and delivered to students in the classroom (or otherwise at an assigned time or place); and this is so even when a permanent record of the delivery of the course is simultaneously made, as in the case (for example) of a videotaped recording of a lecture. To this extent "the immediate content" of the course is subject to the License.
- 2. Recording of lectures may only be done with the permission of the instructor presenting the lecture. Once given, such permission may be withdrawn for particular lectures or for portions of lectures. Permitted recordings of lectures may be archived by the University library. Any access to such archived recordings shall be for private scholarly purposes only. Such archived recordings, the time for which they will be retained, and their distribution for scholarly purposes, or any other purpose, shall be subject to limitations defined in writing to the University Archivist by the instructor.

Student recording of lectures, when permitted by the instructor, shall be for private study only. Such recordings shall not be distributed to anyone else without authorization by the instructor whose lecture has been recorded. However, the instructor may arrange through the Office of Information Technology to make recorded lectures available to students enrolled in the class on such terms and conditions as he or she prescribes. Unauthorized distribution is a cause for disciplinary action by the Judicial Board.

A [check sheet](#) shall be completed by the instructor at the beginning of each semester. The instructor shall maintain a copy and retain one in the departmental files. S/he should communicate to the students in the class what, if any, permission has been granted to tape the course content.

- 3. But works which are created outside the classroom (or otherwise beyond the immediate temporal setting in which a course is taught or delivered) - works (for example) such as books, texts, articles, notes for lectures, outlines, photographs, videos, films, recordings, audiovisual works and the like - are not part of "the immediate content" of a course, even if they are created expressly for the purpose of being assigned or used (in whole or in part) in the actual teaching or delivery of a course. Rights in these works are not subject to the License created by this Policy, though of course they remain subject to other more general legal or customary principles applicable to fair use, whether in the academy or elsewhere.
- C. The License shall be presumed to spring into existence automatically, by virtue of a course's approval for credit by Duke with the consent of any individual rights-holder; no additional formality shall be required. No royalty shall be payable for the License, sufficient consideration for which shall be deemed to reside in the mutual benefit realized by Duke and the consenting rights-holder, as well as by the individual members of the university community.
- D. The License shall include a particular right in students duly enrolled in a course to take class notes for their personal use; but notes in a course shall not be taken or disseminated for commercial purposes unless approved by the instructor.
- E. The License also shall include a right in Duke to offer the course, or to develop and offer derivative courses of instruction, in both conventional and non-conventional settings (including

courses intended for use in internet distance education projects), whether at Duke or elsewhere. The License shall continue to be available to Duke even if the faculty member in whom individual rights otherwise vest should leave Duke.

- F. No claim of rights in teaching style or the like will be recognized under this Policy; but individual instructors may claim personal rights of privacy against non-consensual commercial exploitation of their name, likeness or private personality.
- G. A willing instructor who creates a highly original or singular course ordinarily may expect a preference (as against the claims of others) with respect to any assignment to teach that course (whether in conventional or unconventional settings) from time to time; but no continuing entitlement is implied as against reasonable administrative considerations to the contrary, including the particular demands or prerequisites of the curriculum.

IV. Particular Provisions Applicable to Internet Distance Education Projects

Given the increasing presence of digital technologies, and the growing likelihood that distance education projects via the internet may bring about significant changes in the practices and fortunes of the academy, it appears prudent to establish additional provisions particularly applicable to such projects:

- A. Duke may appropriately consider any internet distance education project that offers the promise of securing and advancing Duke's place among the leading universities of the world. To that end, Duke may participate in the development of such projects with members of its own community; or it may enter into relationships with persons outside the established academic community. In either case, it may enter into such projects on terms and conditions which are fair and reasonable in the circumstances, whether or not they are customary in the academy, so long as they do not adversely affect the fundamental principles of governance, tenure and academic freedom otherwise recognized in conventional settings at Duke from time to time.
- B. An individual member of the Duke Faculty, who is employed on a permanent full time or equivalent basis, and who intends to enter into any non-Duke internet distance education project in which he or she proposes to teach a course regularly or recurrently, shall first disclose the proposed undertaking in advance to his or her Dean or Department Chair (or their designate), who will examine the proposed undertaking in order to insure that no conflict of interest or commitment will arise.
 - 1. Conflicts of interest or commitment will be addressed generally in accordance with the terms of the University Policy on Conflicts of Interest in force from time to time.
 - 2. In addition, a conflict of interest or commitment will be presumed to arise under this Policy on Intellectual Property Rights:
 - a. when an individual proposes to teach a non-Duke internet course substantially equivalent to a conventional course he or she is regularly assigned to teach at Duke;
 - b. when an individual proposes to teach a non-Duke internet course in circumstances likely to be directly competitive with an existing or proposed Duke internet course which he or she has been offered an opportunity to teach;
 - c. when an individual proposes to participate in teaching a non-Duke internet course in circumstances likely to confuse or mislead the public with respect to his or her primary obligations or allegiance as a member of the Duke Faculty; or
 - d. when an individual proposes to participate in teaching a non-Duke internet course in circumstances likely to impair the continuing performance of his or her primary responsibilities at Duke.

The Dean or Department Chair (or their designate) who examines a proposed undertaking in which a conflict of interest or commitment presumptively arises under this Sub-Paragraph (2) may determine that the conflict is trivial, or that it can be cleared on terms reasonably calculated to serve the best interests of Duke and the individual faculty member alike, and in either case shall give notice to that effect in writing within ninety days, both to the individual and to the Provost; but in the absence of such a determination the individual shall not proceed further with the undertaking as proposed while remaining a member of the Duke faculty.

A faculty member who has engaged appropriately in a non-Duke distance education project as provided above shall nevertheless repeat the process of notice and clearance annually thereafter with

respect to his or her continuing participation in that project. If changed circumstances thereafter create a conflict as provided above, and the conflict cannot reasonably be cleared, the faculty member will withdraw from the project within one year of the date when the existence of that conflict is determined.

C. The University Intellectual Property Board (established by Article VIII of this Policy) may develop additional interpretations or regulations reasonably designed to implement these provisions, and may promulgate additional requirements with respect to prior notice and clearance. But the purpose of all such additional interpretations, regulations or requirements will be to avoid unreasonable conflicts and the appearance of evident professional impropriety, rather than to limit unduly an individual's ability to engage in suitable outside professional activities, including distance education projects; and to that end, Duke will exert reasonable efforts to clear such conflicts and to eliminate any appearance of impropriety through appropriate disclaimers, licenses or the like.

V. Provision for Declaring Extraordinary Exceptions

The Provost, acting upon the advice or recommendation of the University Intellectual Property Board, and with the concurrence of the Executive Committee of the Academic Council, may declare additional exceptions to these principles prospectively, on just and reasonable terms, when a particular transaction or category of work appears to require extraordinary treatment. Works created specifically for or in the context of the emerging digital or internet environment, and particularly when intended directly for use in distance education ventures in which the University proposes to invest its own singular identity, may justify extraordinary treatment more often than do works in traditional media. Exceptions limited to compulsory non-exclusive licenses from an individual creator to Duke, accompanied by suitable provisions for royalty payments by Duke, will appear just and reasonable more often than will appropriations of a creator's entire intellectual property rights in a work.

VI. Moral Rights

The moral rights of each individual creator will be respected to the extent practicable in every case contemplated by this Policy; and in no case will the University fail to recognize an individual creator's entitlement to acknowledgment, attribution or other appropriate credit, to the fullest extent practicable.

VII. University Name and Identity

- A. Intellectual property rights arising in Duke University's name, logos and other impedimenta of identity belong to Duke. Such rights may be licensed from time to time upon suitable terms and conditions approved by the President or his/her delegates, taking into full and appropriate account the research, teaching and collegial missions of the University.
- B. Members of the Duke Community may identify themselves as such from time to time, with such indicia of their status as is usual and customary in the academy; but any use of Duke's name, logos or impedimenta of identity shall be reasonably calculated to avoid any confusing, misleading or false impression of particular sponsorship or endorsement by Duke, and when necessary shall include specific disclaimers to that end.

VIII. University Intellectual Property Board

- A. This policy shall be interpreted and administered by a new University Intellectual Property Board, to consist of seven members appointed by the Provost, no fewer than four of whom shall be members of the faculty nominated by the Executive Committee of the Academic Council (and from among whom the Committee's Chair shall be appointed). Members of the Board shall serve initial terms of one to three years (as designated by the Provost); upon the expiration of each such initial term, successor members of the Board shall be appointed thereafter for a term of three years. A member may be reappointed from time to time upon renomination.
- B. The Board shall publish such additional interpretations, regulations and requirements, and shall take such other administrative actions, as are necessary to the suitable discharge of its duties and the adequate functioning of this Policy, including specific provisions for the further appointment

of its members; but in every case the Committee's interpretations, regulations and requirements, as well as its administrative actions, shall be consistent with the provisions expressed in this Policy.

- C. The University Patent Policy Committee (formerly known as the University Intellectual Property Committee), shall have jurisdiction over the University Patent Policy, as further provided in Article XD. hereof.

IX. Appeals and Arbitration

A person aggrieved by the proposed application of any provision of this Policy may appeal within six months from the appearance of such grievance for a plenary ruling, on such grounds as appear relevant, just and reasonable, first, to the Provost of the University (or the Provost's delegates), who shall give decision within no more than ninety calendar days from the lodging of the appeal; and second, within ten business days after the Provost's decision, to the President of the University (or the President's delegates), who shall give decision in no more than ninety days from the date of the Provost's decision, and whose ruling shall end the University's claim of appellate jurisdiction in the matter. Thereafter, the aggrieved person may proceed as of right to binding arbitration before a single arbitrator pursuant to the commercial arbitration rules of the American Arbitration Association. Each party shall bear its own costs in connection with the proceedings; but in the event an Arbitrator finds that a party has proceeded in bad faith the Arbitrator may award costs and expenses (including attorneys' fees) to the other party.

X. Effective Date; Prior Works

- A. This Policy shall take effect upon approval by the President and the Provost, when concurred in by the membership of the Academic Council, and by the Board of Trustees of the University.
- B. The 1996 University Policy on Copyrightable Work shall be superseded by this Policy upon the effective date hereof.
- C. This Policy on Intellectual Property Rights shall constitute the sole Duke University Policy governing all non-patent intellectual property rights of every kind arising in any work of the intellect (cf, Article I, fn 1), and in any medium in which the work may be embodied or expressed.
- D. This Policy on Intellectual Property Rights, and the Policy on Inventions, Patents, and Technology Transfer (effective July 1, 1996) (the Patent Policy), shall be construed in *pari materia* so as to give reasonable force and effect to the provisions of both policies. Otherwise, the Patent Policy shall not be affected in its application to the disclosure and subsequent management of inventions, patents or technology transfers; and the jurisdiction of the Patent Policy Committee with respect to the Patent Policy shall continue unabated, *pro tanto*.
- E. In the event of any conflicting interpretation of the two Policies by the Intellectual Property Board and the Patent Policy Committee, the President, the Provost, and the Chair of the Academic Council (acting jointly as a committee of the whole, to be chaired by the President) shall resolve the issue promptly; and their decision in the matter shall be binding upon both the Board and the Committee. In such a case, a "person aggrieved" by their decision (as contemplated in Article IX of this Policy) may elect thereafter to appeal as provided or to proceed directly to arbitration.
- F. Intellectual property rights in works created prior to the effective date of this Policy shall be treated in accordance with the principles articulated herein, to the extent that such treatment is practicable, just and reasonable.

Duke University Copyright Guidelines for Electronic Course Content

Duke University expects all members of the University community to respect copyright law (Title 17 of the United States Code). The principles of copyright law that apply to electronic course content are the same as those that apply to printed course material, regardless of whether the electronic content is textual or audio-visual, or where it is stored (e-reserves, AFS, Blackboard, iTunesU, for example). If permission would be required for a print use, it will be required for an analogous electronic use.

Duke also affirms that the exceptions to a copyright owner's exclusive rights that are provided by the law, especially the fair use provision, are integral to the balance between exclusive rights and productive, socially beneficial new uses of works. Fair use requires a fact-specific analysis that should be considered carefully whenever deciding whether or not permission is required.

The digital age has made potential course content available in a wide variety of ways, and faculty can often choose amongst several formats to make reading, viewing and listening materials available to students. If it is possible to link to material that is either publicly available on the Web or available to the Duke community through a database licensed by the University Libraries, further permission is not needed to use that material.

When it is necessary to make a copy of the material, rather than simply linking to it as described above, permission is not needed if the works are in the public domain (generally, material published before 1923) or are offered freely under a Creative Commons license. For other material, a fair use analysis should be considered; if fair use is determined not to apply to the specific use, permission must be obtained.

A fair use analysis is based on four factors found in section 107 of the Copyright Act: the purpose and character of the use, the nature of the copyrighted work, the amount and substantiality of the portion used in relation to the entire work and the effect of the use on the potential market for or value of the copyrighted work. A detailed explanation of the application of these factors is available at <http://library.duke.edu/blogs/scholcomm/copyright-in-teaching/> and the checklist that follows can help guide a reasonable decision about fair use. For many activities at Duke, these circumstances will be especially important when relying on fair use:

- Your use is nonprofit and educational,
- You are using only a small part of a work and no more than is needed to accomplish your teaching objective, and
- Access to the portion of a copyrighted work is restricted to students registered for the specific class in which it is needed.

For each use for which fair use is claimed, a copy of the completed checklist can be retained to show the good faith of that claim; this is especially important when all of the above circumstances do not apply to a particular use.

When relying on fair use, materials should be attributed properly and marked to indicate that they are subject to copyright protection. As noted above, copyright protected course content should be kept behind password barriers so that only students in the class can access it. Information about creating password protection for electronic course content can be found at <http://cit.duke.edu/ideas/how/copyright.html>. Materials should remain available only for a limited time, usually no longer than necessary for a particular class use.

When permission is needed, for example where a large portion (several chapters) of a book is used, the Copyright Clearance Center (<http://www.copyright.org>) can usually assist in obtaining and collecting fees for the necessary authorization. If analogously large portions of audio or video recordings are used, similar collective permission organizations may exist, or the distributor can be contacted directly. When permission is not available after reasonable efforts or a rights holder can not be found (so-called "orphan works"), a persuasive fair use analysis becomes more likely.

Questions regarding these Guidelines may be directed to Kevin Smith, Duke University Libraries (<mailto:kevin.l.smith@duke.edu>), or Henry Cuthbert, Associate University Counsel (<mailto:henry.cuthbert@duke.edu>).

Checklist for Fair Use Analysis

This checklist is a tool to assist you as you apply the fair use balancing test to specific situations in which you want to use copyrighted materials. If a particular use is fair use, it may proceed without authorization from the copyright owner; if the use does not fall within fair use, permission is necessary.

The fair use analysis is always circumstantial and never entirely certain. For each of the four fair use factors below, determine whether each listed circumstance favors or disfavors fair use based on the specific material in question and the use desired. Where the circumstances favoring fair use outnumber those against it, you can feel comfortable in relying on the fair use exception. Where less than half the circumstances favor fair use, you should seek permission or consider alternatives to using the work as planned. If the factors appear evenly split or you have questions about interpretation, please feel free to contact Kevin Smith, Duke University Libraries (<mailto:kevin.l.smith@duke.edu>), or Henry Cuthbert, University Counsel's Office (<mailto:henry.cuthbert@duke.edu>).

FACTOR ONE – PURPOSE OF THE USE

Favoring Fair Use

- Educational
 - Teaching (including multiple copies for classroom use)
 - Research
 - Scholarship
 - Criticism
 - Comment
- Transformative or Productive use (Changes the work to serve a new purpose)
- Nonprofit use.

Disfavoring Fair Use

- Commercial, entertainment or other use.
- Verbatim or exact copy, not transformative.
- Profit generating use.

FACTOR TWO – NATURE OF THE COPYRIGHTED MATERIAL

Favoring Fair Use

- Factual, nonfiction, news
- Published work

Disfavoring Fair Use

- Creative or consumable work. (art, music, feature film, fiction; workbook, case study or test)
- Unpublished work

FACTOR THREE – AMOUNT COPIED

Favoring Fair Use

- Small quantity used (e.g. single chapter or journal article, other short excerpt (less than 10-15% of the whole work)).
- Portion used is not central to work as a whole.
- Amount is appropriate to the educational purpose.

Disfavoring Fair Use

- Large portion or entire work.
- Portion used is central or the “heart” of the work.
- Includes more than necessary for educational purpose.

FACTOR FOUR -- EFFECT ON THE MARKET FOR THE ORIGINAL

Favoring Fair Use

- No significant effect on the market or potential market for the copyrighted work.
- One or few copies made and/or distributed.
- No longer in print; absence of licensing mechanism.
- Restricted access (limited to students in a class or other appropriate group).
- One-time, spontaneous use (no time to obtain permission).

Disfavoring Fair Use

Cumulative effect of copying

Patent Agreement

This agreement is made by me with Duke University in consideration of my employment and/or my utilization of university research facilities.

I agree to notify the University (or any individual, corporation or governmental agency which the university may specify) promptly of any invention which I believe to be patentable and which I conceive or develop while employed by the University or while using any university research facilities, in order that determination of the rights and equities in such invention may be made in accordance with the Duke University Policy on Inventions, Patents, and Technology Transfer.

In the event the University desires to seek patent protection on any such invention which has been determined to be university property, I agree to assign to the University all my rights, title, and interest in and to such invention and to supply all information and execute all papers necessary for the purpose of prosecuting patent applications thereon. I understand that expenses for making such assignments and procuring such patents shall be paid by others than myself. I also understand that the University reserves the right to abandon the prosecution of any patent application.

If the University receives revenue from patents on inventions assigned by me pursuant to this agreement, I understand that I will share in these funds according to the distribution schedule set forth in the patent policy.

I further agree to do all things necessary to enable the University to fulfill its obligations to any person, corporation, or other agency sponsoring the particular research projects in which I am or may be engaged.

I understand that this agreement is part of the terms of my employment and that any contract of employment heretofore or hereafter entered into between me and the University shall be deemed to include this agreement except to the extent that an express provision of such contract of employment is inconsistent therewith.

_____	_____
Name (Print or Type)	Signature
_____	_____
Department	Date

University-Industry Guidelines

Preamble

Duke University wishes to increase its cooperation with private industry in the search for new and useful knowledge. Duke believes that, while maintaining academic traditions and values that advance the search for truth through free inquiry, it can find ways to combine its unique resources with the resources of private industry to investigate important questions of interest to the research sponsor, the university, its faculty, and the public as a whole. This document is a statement of principles and policies that will guide Duke in establishing fruitful research joint ventures with private firms.

There are, to be sure, certain potential conflicts between the missions of academic institutions and industrial sponsors of research. A fine university perceives its *raison d'être* to be the generation and dissemination of knowledge for the benefit of society as a whole; viewing knowledge as a public good, a university subscribes to the scientific tradition of fully and promptly making public all research findings so that others may build upon them. Industry, on the other hand, is usually interested in recouping and profiting from its investments in research by capturing, rather than freely sharing, the value of new knowledge. Universities are also interested primarily in pursuing fundamental research and are less interested in applications than industrial firms are apt to be.

Largely because of these differences in outlook, the production of new knowledge in the United States has in the past been rather rigidly divided between a public sector producing public goods (with universities supported by governments and philanthropy as a vital element) and a private sector producing information for proprietary use. The barriers between these two sectors may have inhibited the production of valuable knowledge by making it difficult to bring together the unique resources available only in universities with the private capital and research capabilities of industrial firms. While useful collaboration has occurred, the public would benefit substantially if the conflicts perceived between the public responsibilities of universities and the private interests of corporate research sponsors could be resolved in light of a higher common objective, the search for truth.

Duke believes that the overarching value to be served in these matters is the pursuit of useful knowledge and that this goal can be advanced both through maintenance of its own academic and scientific traditions and through cooperative projects with interested parties. Where these two paths to new knowledge necessarily diverge, Duke will seek to accommodate the conflict whenever possible. In cases where the university is convinced that special arrangements are necessary to protect a research sponsor's essential interests, Duke will seek a constructive solution to a sponsor's problems within the policy limits described here. However, as noted in detail below, Duke must also be satisfied that its own commitments to free inquiry, to education, to collegiality within the university, and to enlarging the common pool of knowledge will not be prejudiced by the terms of any particular arrangement.

The establishment and maintenance of research relationships with industry will be facilitated if all parties recognize from the beginning that the university adheres to certain principles and is guided in its actions by certain policies. For such policies to be effective in a rapidly changing environment, such as we have today, they must be wisely and flexibly interpreted. Interpreting the policies given below will be the responsibility of the Research Policy Committee, which it is recommended be created with the approval of this policy document. This committee is charged with advising the provost regarding the implementation of these policies, as well as with recommending those changes in the policy that may prove necessary or advisable.

The overriding goal of this policy is to promote close and imaginative working relationships between the university and industry that will nurture the development of new knowledge while still maintaining the integrity and independence of the university, its faculty, and students.

Section I: Policy

Acceptance of a Research Project

Circumstances may arise where it is considered to be in the university's best interests for a particular principal investigator to do certain research for a sponsor. In such cases, the investigator may feel some pressure to participate in such research. It is especially important that investigators be free not to accept grants or contracts that, in their view, circumscribe their independence or control of their professional work.

POLICY: No principal investigator shall be required to participate in a particular research effort as a condition of employment at the University.

Direction of Research. Limits on the Sponsor's Power to Direct or Control Research

While public or private research sponsors may reasonably expect to define broadly the project they will support, university principal investigators may expect to have wide discretion in designing and modifying their sponsored research. Although the sponsor may consult on matters of concern, generally it is not appropriate for a sponsor to specify in detail how the work is to be done.

POLICY: A sponsor shall have the privilege to define broadly the topic of the research to be funded. The university principal investigator shall have final authority over the design and control of that research.

Limits on the Control of Sponsors Over the Scope of Legally Free-Standing Research Units

From time to time the university may choose to establish, in cooperation with a sponsor or sponsors, a research institute, center, or program that is legally free-standing from the university, but that depends upon faculty of the university for partial staffing. In such a situation, a sponsor may seek a formal voice in how its committed funds are spent. The situation, while offering important opportunities, also poses certain risks. In particular, if inappropriate control over the unit's research program is provided to the sponsor, the academic freedom of the faculty involved may be diminished.

POLICY: The University shall not participate in a joint free-standing research unit that would restrict the academic freedom of the faculty. The provost, advised by the Research Policy Committee, shall determine whether this risk exists and, if so, whether the level of risk is acceptable. The review by the committee and the provost shall take place before the university decides whether to enter into an agreement to create such a unit.

Publication

Tradition has long held that university researchers must be free to publish their research results. This freedom is essential if the university is to be the source of new knowledge for society. Therefore, it must be vigorously guarded. At the same time, good business practice requires that sponsors protect their proprietary rights, trade secrets, or other confidential information. These separate and legitimate interests may diverge on questions relating to publication. Clearly, it is in both the researcher's and the sponsor's best interests to find ways to protect academic freedom while at the same time meeting the nondisclosure requirements of the sponsor.

There are three ways in which a sponsor may affect the process of publication: by reviewing materials prior to publication; by delaying the date of publication; and by preventing publication.

Review Prior to Publication and Resulting Delay

The university has traditionally allowed a sponsor to review materials prior to publication, but such review has been allowed only under certain circumstances and has been limited to a reasonable period of time. This practice has been followed in order to prevent inadvertent disclosure of a sponsor's proprietary information and/or to allow the sponsor time to file proper proprietary protection on research-generated technology. Such a review may delay publication for no more than a brief period.

POLICY: A sponsor may, prior to publication, review materials resulting from research it has sponsored in those cases where possible proprietary right may be involved or where the University has been provided a sponsor's proprietary information. Such reviews should not delay publication for more than ninety (90) days, except with the approval of the provost.

Preventing Publication

While having due regard for the sponsor's interests, the university encourages the publication of research results. The university must retain final authority over publication rights, including the right to publish. As a matter of policy, the final determination of what may be published or not published normally will remain with the University.

POLICY: Final determination of what may be published or not published shall remain with the University. The University will also retain the right to make a final determination with respect to publication of computer programs. Exceptions may be granted by the provost only after detailed review and upon the advice of the Research Policy Committee.

Communication among Research Colleagues

When a sponsored research project deals with proprietary information, the sponsor may wish to restrict the researcher's freedom to discuss the research with colleagues. While recognizing the need for researchers to protect the sponsor's proprietary rights, the university recognizes a concomitant responsibility to honor the researcher's membership in an intellectual community. It is essential that the free exchange of ideas among colleagues not be inappropriately restricted.

POLICY: Agreements to treat as confidential information generated by research done at the University are ordinarily unacceptable. There may, however, be situations where exceptions to these guidelines are consistent with the university's educational, professional, and scholarly principles. Such exceptions are granted by the provost only after detailed review and upon the advice of the Research Policy Committee.

It is also the responsibility of each individual researcher to protect freedom to communicate with colleagues and to refuse to enter into sponsored agreements that will restrict that freedom in unreasonable or unacceptable ways.

Freedom to Do Related Work

One potential concern of a sponsor may be that a faculty member whose research it is funding will do closely similar research for a second sponsor. This could undermine the first sponsor's competitive and legal position. To address this concern, the sponsor may sometimes ask the university to include language in the sponsoring contract assuring that such parallel research will not take place. The university has a different concern: that such language might limit the academic freedom of the researcher to do research in related but different areas.

POLICY: A sponsor may request that, prior to entering into additional sponsored research agreements to do research that is closely similar to the research sponsored by that sponsor, a researcher will notify the sponsor of that intention. In such situations, the University will only consider restricting the freedom of the researcher to do such related work if the first sponsor raises a concern about protecting its proprietary rights prior to the signing of the second agreement. The University will agree to restrict the activities of a researcher to do related work only if there is a reasonable possibility that the work done for the second sponsor will infringe on the proprietary rights of the first sponsor under the pre-existing sponsored agreement.

Best Efforts

A sponsor making a financial commitment to a particular research project may desire to reduce its risk by stipulating the expected results as specifically as possible. While recognizing the sponsor's right to require reports to be provided by certain dates, the university is not able to guarantee to a sponsor that a particular research project will succeed or produce particular results. Instead, the university will commit to using best efforts in conducting a research project.

POLICY: Since state-of-the-art research is by nature unpredictable and without guarantee of success, research within the University is conducted on a best efforts basis. However, a good faith effort will be made to organize research projects in a manner that is sensitive to the special needs and time constraints of the sponsor.

Graduate Student Involvement

- A. Graduate Students and Proprietary Information. An essential aspect of education, in particular graduate education, is the development and dissemination of new knowledge through publication of research results. This reflects the academic community's belief that the sharing of knowledge advances knowledge. In this

context, the use of confidential information in research poses risks. When faculty participate in research that involves the handling of proprietary information, the university believes that a student's participation under such circumstances should be monitored by a third, disinterested party.

POLICY: In general, students shall not participate in projects that, because of confidentiality or other factors, might constrain their right to publish or communicate freely. Exceptions to this policy must be approved in writing by the student's chair (or chairs, if the faculty member is in a second department) or dean (or deans if the faculty member is in a second school). The student shall also sign this document to signify understanding of the issues involved. Copies of the signed document must be sent to both faculty member and student before the student may become involved in the project.

- B. Graduate Student Involvement in Faculty's Outside Professional Activities. The university recognizes that benefits may accrue to students, and in particular graduate students, who are able to participate in the outside professional activities of faculty. Such participation may result in intellectual growth, the acquisition of new skills in frontier areas of knowledge, and additional income. At the same time, it is understood that these arrangements are likely to change the relationships between faculty and student in ways that are not always desirable. For example, a graduate student who, though very able, is not making satisfactory progress toward a degree because of absorption in a faculty member's growing new business, may present a dilemma for the instructor/supervisor. It should be added that the dilemma is one that the student may well be unaware of or unconcerned about. Most students welcome involvement in a faculty member's outside professional activity, and may not realize the potential problem the situation may create for the faculty member.

POLICY: To protect the student and the University, the appropriate chair and dean must give prior approval, in writing, for any involvement of students in the outside professional activities of faculty. The student must also sign this document, to signify understanding of the issues involved. Copies will be sent to both faculty member and student. The chair or dean is asked to review the case with particular care when the faculty member is the student's thesis advisor or supervisor as a teaching assistant, or if the student is already working full-time as a research assistant. In situations where, in the chair's and dean's judgment, the quality of the student's education or other university interests are in jeopardy, such arrangements should not be approved.

Conflict of Interest or Commitment and Outside Professional Activities

- A. Definitions of Conflict of Interest and Commitment. Conflict of Interest: a conflict of interest can be said to exist when a member of the university community has a relationship with an outside organization such that his or her activities within the university could be biased by that relationship in a direction that would ultimately provide direct financial benefit to the individual or a close family member. Conflict of commitment: a conflict of commitment can be said to exist when a member of the university community has a relationship that requires a commitment of time or effort to non-university activities such that an individual, either implicitly or directly, cannot meet the usual obligations to the university. Obligations to the university are not discharged solely by meeting classes but require availability of faculty to students outside the classroom, participation in various committees, supervision of graduate and postdoctoral students, and progress in research programs. Any relationship with an outside organization that requires frequent and/or prolonged absence from the university presents a conflict of commitment.

POLICY: Faculty members shall avoid relationships that constitute a conflict of interest or a conflict of commitment.

- B. Conflict of Interest Procedures

1. Disclosure to Chairs/Deans: It has long been recognized that consulting, in certain situations, can create in a faculty member a conflict of interest or commitment. The university's policy of restricting a faculty member's consulting to one day a week addresses this issue in part. Other situations in which faculty may face a conflict of interest or commitment include ownership (or management responsibilities) by a faculty member or his or her immediate family of a significant financial interest in an outside concern. Immediate family are defined as spouse and minor children.

POLICY: To assure that chairs and deans are informed about arrangements that may pose a conflict of interest or commitment, faculty members shall disclose to their chair or dean once a year and in writing their outside relationships with corporations or other business entities, as consultant, advisor, or manager. Information disclosed must include the name of the company, and the nature and scope of the relationship. No information about financial arrangements need be provided.

2. Disclosure to Senior Administrators

POLICY: Direct and active management obligations in such an enterprise raise the possibility of a conflict of interest. A faculty member is required to notify the provost in writing prior to accepting any such direct and active management obligation, and may assume that no conflict of interest exists unless otherwise notified by the provost. The provost may, at the time of acceptance or at a later time, require appropriate action to assure that no conflict of interest exists.

3. Research Policy Committee

POLICY: In cases where a faculty member wishes to appeal an interpretation or decision made under this policy by a chair, dean, or provost, or where a chair, dean, or provost wishes to consult others for advice before making such a decision, the case may be brought to the Research Policy Committee. On request from a faculty member, chair, dean, or provost, the committee shall review the status of that faculty member's (or his or her immediate family's) new or continuing significant financial interest in or managerial relations with a private enterprise. The committee shall report to the provost whether in their opinion this involvement may pose a conflict of interest or commitment.

4. Definitions of Certain Terms Used in This Policy. Significant financial interest in a private enterprise means holding more than twenty percent of the equity, options, or other types of corporate security. Such interests, if held by a faculty member's immediate family, shall fall within this definition. Direct and active management obligations include serving as a member of the board of directors, chief executive officer, chief operating officer, director of research, treasurer, or other senior line management officer.
5. University Business with Faculty Enterprises. The university's current policy governing its business dealings (i.e., contracts) with companies owned or controlled entirely or in substantial part by faculty is administered at present by the Conflict of Interest Committee. We recommend that the Research Policy Committee implement this policy instead, and that the Conflict of Interest Committee be dissolved.

Section II: Administrative Issues

Research Policy Governance at Duke University

There are at least seven offices and nine committees that have research-related responsibilities at the university. At present, coordination among these units is primarily informal, although individual units have some formal ties to each other as well. These units and their functions are:

Research Administrative Structure

- Office of Research
- Medical Center Development Office
- Office of Research Administration (Medical Center)
- Office of Corporate and Venture Development
- Office of Research Support
- Office of Sponsored Programs
- Office of University Development

Committees/Councils

- Committee on Conflict of Interest
- Institutional Animal Care and Use Committee
- Institutional Biosafety Committee

Institutional Review Board (Medical Center)
Misconduct in Research Committee
University Patent Policy Committee
Research Policy Committee
Small Grants Committee (Medical Center)
University Research Council (non-Medical Center)
University Review Committee on the Use of Human Subjects in Nonmedical Research

Research Policy Committee

The Research Policy Committee is responsible at the request of the provost for reviewing university research policy, maintaining liaison with existing research committees and councils, reviewing major institutional proposals, and smaller proposals that have important policy implications.

Membership

The Research Policy Committee consists of representatives from both the faculty and administration. The committee is chaired by the vice provost for research. Five faculty members, knowledgeable about research and sponsored projects issues and representing a spectrum of fields, shall be appointed by the vice provost for research on the recommendation of the Academic Council and with the concurrence of the provost. Members who serve by virtue of their office or are appointed by a senior administrator are:

- Dean of the Graduate School;
- One member appointed by the chancellor for health affairs;
- One member appointed by the senior vice president for alumni affairs and development;
- One member appointed by the university counsel.

Policy on Research Records: Sharing, Retention and Ownership

As Approved by the Academic Council May 5, 1994

Revised by Research Policy Committee January 2007

The preparation, sharing and retention of appropriate records are essential components of any research endeavor at the University. The University, its faculty and its trainees have a common interest and a shared responsibility to assure that research is appropriately recorded, shared and retained. Original records may be required to protect the University's intellectual property rights, to answer ongoing questions regarding management of a research program, to address possible questions that may arise regarding the propriety of research conduct and to comply with the data sharing requirements of many sponsors. Most importantly, it is essential that original research records be mutually available to all the collaborators on a research project.

Definition of Research Records

Research records include, by way of example but not limitation, material contained in research notes, laboratory notebooks and in other media such as computer disks and instrument printouts. Significant research materials or products generated by any research are also part of the record and should be retained and available.

Sharing of Research Records

Research records must always be available to collaborators (co-investigators, supervisors and their trainees). In collaborative projects, all investigators should know the status of all contributing research records and have access to them consistent with confidentiality restrictions. Investigators also should be aware if their research records are subject to specific data sharing requirements of a sponsor.

Retention of Research Records

Faculty, or the responsible investigators, have the obligation to ensure that, for all aspects of their research program, sufficient records are kept to document the experimental methods and accuracy of data collection as well as the methods and accuracy of data interpretation. This policy does not create an obligation to retain the research records of an unfunded project unless it results in publication or involves the use of animals or human subjects. Research records should be archived for a minimum of five years after final reporting or publication of a project (or longer if required by an external sponsor, law, rule or regulation). The archived records should be the originals. In addition, the records should be kept for as long as may be required to protect any patents resulting from the work. If any questions regarding the research are raised during the required retention period, the records should be kept until such questions are fully resolved. In the event an investigator leaves the University for any reason, the original research records must be retained at the University and the investigator's department and collaborators notified as to their location.

Ownership of Research Records

The primary owner of research records is the University. The University has the right of access to the supporting records for all research carried out through the University with the understanding that information or data that would violate the confidentiality of sources or subjects involved in the research should not be disclosed. In addition, extramural sponsors providing support for research at Duke University may have the right to review any data and records resulting from that extramural support.

Duke University Policy and Procedures Governing Misconduct in Research

Effective November 1995

Revised January 2007

The following policy and procedures shall apply to all research conducted at Duke University. The procedures delineated herein shall be the exclusive method for handling allegations of misconduct in research made against faculty. Allegations involving non-faculty researchers shall typically be handled in accordance with the procedures for those non-faculty groups. However, in all cases in which the research is funded externally, the Misconduct Review Officer (see paragraph one under Procedures below) shall be notified of the allegation and shall determine the procedure to be followed.

Policy

Duke University strives to foster an atmosphere of honesty and trust in which pursuit of knowledge can occur. Integrity of research forms the foundation of respect among scholars and students and between the academic world and the public. All members of the university community share responsibility for maintaining this climate of trust. Occasionally, however, scholars may, inadvertently or not, violate accepted norms of professional behavior, thereby jeopardizing the reputation of the university and possibly damaging their careers and those of colleagues.

Misconduct is especially serious in collaborative research, where the reputations of several researchers pursuing different components of an integrated project may be damaged by the actions of one or more partners. Colleagues in a cooperative venture bear mutual responsibility for ensuring the integrity of research performed and published jointly under their names.

Principal investigators must bear primary responsibility for ensuring the integrity of collaborative research performed under their supervision whether by faculty or non-faculty. Investigators, department and division chairpersons, and center directors are expected to make periodic and reasonable inquiries concerning the integrity of the activities conducted under their supervision.

The policy and procedures concerning misconduct in research are regularly reviewed and modified, as necessary, by the Research Policy Committee, a standing committee of the university. The Committee is also responsible for notifying the academic community of misconduct in research policy and procedures; for ensuring that the research community is educated in the standards for the conduct, reporting, and supervision of research; and for consulting with individuals about the policy and procedures governing misconduct in research.

Misconduct--What Is It?

Misconduct in research is defined as fabrication, falsification, or plagiarism. Fabrication is defined as making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes or changing or omitting data or results such that the research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

In addition, other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting, or reporting research may also constitute misconduct in research. The definition does not include honest error or honest differences in interpretations or judgments of data.

Examples of Activities Representing Misconduct in Research

The following are but examples of misconduct; the list does not include all activities that would constitute misconduct:

1. claiming the ideas or words of another to be one's own;
2. including false statements or data in research proposals, progress reports, publications, or related documents;
3. manipulating research procedures or data so as to bias results; and,

4. misusing confidential material such as manuscripts and grant proposals received in the peer review process and proprietary information or materials.

Examples of Research Practices That Are Inappropriate But Do Not Generally Represent Misconduct in Research

1. maintaining inadequate research records, especially for results that are published or are relied on by others;
2. failing to give appropriate recognition to people who have made significant contributions to the research;
3. conferring or requesting authorship on the basis of a specialized service or contribution that is not significantly related to the research reported in the paper;
4. refusing to give peers reasonable access to unique research materials or data that support published papers;
5. releasing preliminary research results, especially in the public media, without providing sufficient data to allow peers to judge the validity of the results or to reproduce the experiments; and,
6. neglecting to supervise others properly in work for which the faculty member is responsible.

Addressing Additional Issues in the Conduct of Research

Institutional mechanisms are currently in place to address disputes centering on questions of authorship and data utilization (Authorship Dispute Board), financial improprieties (Internal Audit Office), human research subjects (Institutional Review Board), and the use of animals in research (Institutional Animal Care & Use Committee). Although such cases will be reviewed and governed by those bodies as to compliance with relevant regulations and ethical standards, they are not precluded from additional review under the procedures governing misconduct in research. Criminal acts will be handled through the appropriate law enforcement agencies.

Procedures: The Structure

Two parallel structures for handling allegations and investigations of misconduct in research have been established: for the Schools of Medicine and Nursing (Medical Center), the vice chancellor for medical center academic affairs (the vice chancellor) has ultimate authority; for the Schools of Arts & Sciences, Engineering, Earth and Ocean Sciences, Law, and Business (university), the vice provost for research (the vice provost) has responsibility.

Misconduct Review Officer

Two members of the academic administration are designated as Misconduct Review Officers (MRO)--one for the university, appointed by the provost, and one for the Medical Center, appointed by the chancellor for health affairs. The MRO is responsible for:

1. receiving and handling allegations of misconduct in research in the manner provided for in the procedures set forth below;
2. providing necessary administrative support for the relevant Standing Committee on Misconduct in Research and, as necessary, for an ad hoc committee;
3. coordinating communications with the parties involved in the misconduct review process, and maintaining a secure repository for misconduct review documentation; and,
4. taking appropriate action to safeguard and preserve relevant data or evidence relating to the allegation, and/or to ensure the health and safety of patients or personnel at Duke University.

Standing Committee on Misconduct in Research

Two Standing Committees on Misconduct in Research (SCMR) are established—one for the university and one for the Medical Center:

1. the Executive Committee for the Academic Council provides a list of nominees for the University SCMR to the provost, who appoints the University Committee; and,
2. the Basic Science Faculty Steering Committee and the Clinical Sciences Faculty Council on Academic Affairs provide a list of nominees for the Medical Center SCMR to the chancellor for health affairs, who appoints the Medical Center Committee.

The SCMR is responsible for:

1. conducting an inquiry into allegations (with or without admissions of misconduct) referred from the relevant MRO to distinguish between misconduct and carelessness or incompetence;
2. determining if the allegation warrants a formal investigation;
3. advising the MRO of the need to ensure the health and safety of research participants and to preserve and protect physical evidence such as research data; and,
4. reporting to the MRO on the outcome of the inquiry in a written report accompanied by all relevant documents.

Ad Hoc Committee on Misconduct in Research

A decision that an investigation is warranted is made by the vice provost or the vice chancellor (as appropriate), on the basis of the SCMR's inquiry into the allegation or as a result of an appeal by the complainant(s) of the SCMR's finding. If the decision is to proceed with an investigation, the vice chancellor/vice provost will appoint an ad hoc committee to determine whether misconduct occurred. Additionally, a legal advisor shall be appointed to serve the ad hoc committee.

Formation of the ad hoc committee will be governed by two principles: first, the need for total impartiality on the part of the committee members, and second, the need for specific knowledge of the research field.

The ad hoc committee will consist of at least three members selected to ensure that the investigation is carried out as completely and competently as possible. The ad hoc committee may include senior professors and external experts with knowledge of the research field of the individual suspected of misconduct and/or persons with expertise in other areas as necessitated by the nature of the research field or by the nature of the allegations.

Procedures: The Process

Duke University recognizes the importance of addressing allegations of misconduct in research in a timely fashion and with the utmost fairness, sensitivity, and confidentiality. Thus, the university has established a process for handling these allegations. This process is in conformance with guidelines promulgated by the National Science Foundation and Public Health Service; in certain instances, it may be modified to the extent necessary to conform to additional requirements of funding agencies.

To the extent allowed by law, the University shall maintain the identity of respondents and complainant(s) securely and confidentially and shall not disclose any identifying information as it conducts the research misconduct proceeding and any subsequent proceedings, except to:

1. those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and,
2. in the case of research supported by the Department of Health and Human Services, the Office of Research Integrity.

To the extent allowed by law, any information obtained during the research misconduct proceeding that might reveal the identity of human subjects participating in the research shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the research misconduct proceeding.

The procedures outlined below are designed to ensure that charges of alleged misconduct are addressed as judiciously as possible, and that any retaliation against a person bringing an allegation in good faith is strictly prohibited. The objective is to define clearly the responsibility for integrity shared by the Duke community, and to make the preservation of trust more secure.

The Allegation

Any individual having reason to believe that a researcher has committed misconduct in research (as defined above) should report the matter in writing to the researcher's department or division chairperson, division chief, dean, or the appropriate MRO. Allegations addressed to other than a MRO shall be promptly forwarded to the appropriate MRO, who will immediately notify the provost and the vice provost (university) or the chancellor for health affairs and the vice chancellor (Medical Center) that such an allegation has been made.

Appropriate efforts will be made to protect the positions and reputations of those making allegations of misconduct, or providing related information, from any reprisals or retaliation unless those allegations or that information is judged to be baseless and malicious or reckless in nature. If, at any point in the misconduct review process, it is determined that the allegation or information was in fact baseless and malicious or reckless, the matter will be dealt with in accordance with existing university policies and mechanisms, e.g. the Harassment Policy or the Human Resources Work Rules.

Assessment of the Allegation by the Misconduct Review Officer

Within seven (7) days after receiving an allegation of misconduct in research the MRO will assess the allegation to determine if it meets the definition of research misconduct and is sufficiently credible and specific so that the potential evidence of research misconduct may be identified.

Specifically, the MRO will:

1. as necessary, ask the complainant(s) for more information;
2. discuss the allegation with the person(s) accused of misconduct, the respondent(s);
3. determine if the issues which form the basis of the allegation are appropriate for consideration through misconduct review mechanisms, including whether they should be handled through other mechanisms (such as the Authorship Dispute Board, Internal Audit Office, Institutional Review Board, or Institutional Animal Care & Use Committee);
4. refer the matter to the appropriate review body(ies) as necessary. The MRO may consult with others in making this determination and referral; and,
5. as necessary, safeguard and preserve relevant data or evidence and ensure the health and safety of personnel and research subjects.

The confidentiality of the allegation will be maintained to the extent possible.

If, at the conclusion of his or her assessment, the MRO determines that there are no adequate grounds for the allegation and that no further assessment is warranted, the MRO will submit to the vice provost /vice chancellor a written report documenting the reasons for the decision and will advise the complainant(s) of the decision.

If the individual who reported the suspected misconduct disagrees with the conclusions of the MRO's assessment, he or she may make a direct request to the vice provost or the vice chancellor to review the matter. The vice provost/vice chancellor, on his/her own review of the conclusions and circumstances surrounding the allegation of misconduct, may decide that no further action is required or may require a formal inquiry by the SCMR.

If the MRO or the vice provost/vice chancellor determines that the issues are appropriate for consideration through misconduct review mechanisms, the MRO will notify the chairperson of the appropriate SCMR of the need for action and will provide to the chairperson all materials in his or her possession related to the allegation. The MRO will notify in writing the vice chancellor/vice provost, the chancellor for health affairs/provost, the appropriate school dean, the person suspected of misconduct, and the complainant(s) that an allegation inquiry will be conducted under these procedures. The notification will include the substance and the source of the allegation.

Allegation Inquiry by Standing Committee on Misconduct in Research

The appropriate SCMR shall conduct an inquiry into the allegations (with or without admission of misconduct) referred from the MRO or the vice provost/vice chancellor to distinguish between carelessness or incompetence and misconduct; to determine if the allegation warrants a formal investigation; to advise the MRO of the need to ensure the health and safety of research participants, and to preserve and protect physical evidence such as research data; and report to the MRO the outcome of the inquiry in a written report accompanied by all relevant documents.

Prior to or at the beginning of the inquiry, the respondent(s) will be provided written notification of the inquiry and contemporaneously the MRO will sequester all research records and other evidence needed to conduct the research misconduct proceeding. If the inquiry subsequently identifies additional respondents, they shall be promptly notified in writing. A copy of the Duke University Policy and Procedures Governing Misconduct in Research will be provided to all respondents.

Upon notification by the MRO or the vice provost/vice chancellor that an allegation inquiry is required, the chairperson of the SCMR will promptly convene the committee. During the allegation inquiry process, the SCMR shall review available evidence of the alleged misconduct (e.g., plagiarized text, papers containing falsified data,

etc.) to the extent necessary for it to determine whether a formal investigation is warranted. As noted above, the committee shall recommend action as necessary to ensure the health and safety of research participants and to preserve and protect physical evidence such as research data. All individuals involved in the process are expected to cooperate with all efforts to obtain or safeguard data.

The respondent(s) will be given the opportunity to respond to the allegation during an interview with the SCMR, and in writing if desired. The committee may conduct additional interviews with any individuals who may have knowledge of the events in question and may request additional documents as necessary to fulfill its responsibilities. The allegation inquiry will remain confidential to the extent possible.

At the conclusion of its inquiry the SCMR will submit a written report to the MRO; this report shall contain the following information:

1. the names and positions of the respondent(s) and complainant(s);
2. a description of the allegations of research misconduct;
3. any external support involved, including, for example, grant numbers, grant applications, contracts, and publications listing external support;
4. the basis for recommending that the alleged actions do or do not warrant an investigation; and,
5. any comments on the report by the respondent(s) or the complainant(s).

Unless there are extenuating circumstances, the SCMR inquiry shall be concluded within sixty (60) days of inauguration by the MRO. If the report is not submitted within that period, the report will document the reasons for the delay.

If the SCMR determines that an investigation is not warranted, the report will detail the reasons for the determination. The report and all records obtained by the SCMR during its inquiry will be sent to the MRO and will become a permanent institutional record, but no record will appear in the personnel record of the person suspected of misconduct. The MRO will promptly provide a copy of the report to the respondent(s) and to the vice provost/vice chancellor, and will notify in writing the complainant(s) and third parties as necessary of the findings. If the complainant(s) disagrees with the conclusions he/she may submit, within seven (7) days of receipt of the SCMR notification of findings, a direct written request to the vice provost/vice chancellor to review the conclusions. The vice provost/vice chancellor shall review the material received from the SCMR, and shall determine either that no further action is required or that investigation by an ad hoc committee is warranted.

If an investigation is determined to be warranted, the MRO will provide a copy of the SCMR's report and all relevant documents to the respondent(s) and to the vice provost/vice chancellor, advise the complainant(s) of the conclusions, and advise third parties on a need-to-know basis. In such cases, any written comments from the respondent(s) must be provided to the MRO within fourteen (14) days of receipt of the allegation inquiry report; these comments shall be appended to the report.

Investigation by Ad Hoc Committee

On the basis of the SCMR's allegation inquiry, and/or an appeal by the complainant(s) of the SCMR's finding, the vice provost/vice chancellor shall determine in writing whether an investigation is warranted. If an investigation is deemed to be warranted, the vice provost/vice chancellor will appoint an ad hoc committee to determine whether misconduct did or did not occur. The vice provost/vice chancellor also will appoint a legal advisor to serve the ad hoc committee. The MRO will promptly provide to the chairperson of the ad hoc committee the entire record amassed by the SCMR.

The university shall take all reasonable steps to ensure an impartial and unbiased research misconduct proceeding: those conducting the investigation shall be selected on the basis of the expertise that is pertinent to the matter and, prior to selection, potential committee members shall be screened for any unresolved personal, professional, and/or financial conflicts of interest with the respondent(s), complainant(s), potential witnesses, or others involved in the matter. Any such conflict that a reasonable person would consider to demonstrate potential bias shall disqualify the individual member from selection for service on the ad hoc committee.

Within thirty (30) days after the submission of the SCMR's report to the MRO, the ad hoc committee will initiate its investigation into the alleged misconduct. The ad hoc committee is authorized to obtain expert consultation and to secure any necessary documentation or data, and all personnel are obliged to cooperate.

The respondent(s) shall be notified in writing of the allegations to be investigated. Such notice will be sufficiently in advance of the interview with the ad hoc committee to allow for interview preparation. The respondent(s) shall also receive written notice of any new allegations within a reasonable time after the ad hoc committee makes a determination to pursue allegations not addressed in the inquiry or in the initial notice of the investigation. The respondent(s) will have access to materials used in the investigation, but will not be provided with committee minutes, summaries or notes prepared by the committee or individual committee members, or other deliberative documents. Throughout the investigation, the person suspected of misconduct has the right to legal counsel at his/her own expense; such legal counsel may be present during interviews by the ad hoc committee but may not speak on behalf of the respondent(s). Counsel's role will be as an observer who may advise the respondent(s) in private, but without material disruption of the progress of the investigation.

Interviews will be conducted with the complainant(s) and respondent(s), as well as others who might have information regarding key aspects of the allegations; refusal to participate will be dealt with according to existing university mechanisms for upholding faculty and employee standards of conduct. Written summaries of interviews will be provided to the interviewed party for comment, and written comments received from the interviewed party will be included in the record.

It is recognized that new elements of misconduct may come to light during the investigation; this information will be considered. The point at which the additional information or an additional allegation of misconduct is received, as well as its relation to the original allegation, will be considered in decisions as to whether the information or allegation is treated as a separate issue or as part of the current investigation. The MRO will inform the respondent(s) promptly of any additional acts potentially constituting misconduct in research which have been identified, and the manner in which that information will be reviewed.

In sum, in conducting an investigation the ad hoc committee shall:

1. make diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations;
2. interview each respondent(s), complainant(s), and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent(s), and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of investigation; and,
3. pursue diligently all significant issues and leads discovered that are determined to be relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.

The ad hoc committee will prepare its final report within one hundred and twenty (120) days of initiation of the investigation unless there are extenuating circumstances. In developing its findings, the ad hoc committee shall act by simple majority vote of the committee members, based upon the preponderance of evidence

The ad hoc committee's report, in draft form and without any recommended course of action or sanctions, will be made available by the MRO to the respondent(s) and, if deemed appropriate, to the complainant(s), so as to resolve, if possible, any fundamental factual discrepancies. Concurrent with the provision of the draft report, the respondent(s) will be provided either supervised access to the evidence on which the report is based or copies of such evidence, unless such evidence had been provided previously to the respondent(s). The respondent(s)—and complainant(s), if applicable—will have thirty (30) days to provide written comments to the MRO. These comments will be considered by the ad hoc committee in its preparation of its final report, to which such comments will be attached.

The final report of the investigation will do the following:

1. include a list of the committee members;
2. describe the nature of the allegations of research misconduct;
3. describe how and from whom information was obtained;
4. list the individuals interviewed by the committee;
5. describe and document the external research support related to the case, including, for example, grant numbers, grant applications, contracts, and publications listing sponsored support;
6. describe the specific allegations of research misconduct considered in the investigation;

7. include the institutional policy and procedures under which the investigation was conducted;
8. identify and summarize the research records and evidence reviewed during the investigation, and identify any evidence sequestered but not reviewed. The report should also describe any relevant records and evidence not sequestered and explain why.
9. provide a finding as to whether research misconduct did or did not occur for each separate allegation of research misconduct identified during the investigation, and if misconduct was found,
 - a. identify it as falsification, fabrication, or plagiarism (or another form of misconduct in research) and whether it was intentional, knowing, or in reckless disregard,
 - b. summarize the facts and the analysis supporting the conclusion and consider the merits of any reasonable explanation by the respondent(s) and any evidence that rebuts the respondent's explanations,
 - c. identify any relevant external support,
 - d. identify any publications that need correction or retraction,
 - e. identify the person(s) responsible for the misconduct, and
 - f. list any current support or known applications or proposals for support that the respondent(s) has pending; and,
10. include any written comments made by the respondent(s) and/or complainant(s) on the draft investigation report.

The report will be addressed and delivered to the vice provost/vice chancellor. A copy of the final report will be provided to the MRO and respondent(s), and the complainant(s) will be informed of the ad hoc committee's findings by the MRO.

If, on the basis of the investigation, an individual is found to have engaged in misconduct, the report will also recommend an appropriate course of action. The recommended action may include sanctions as well as adequate steps to ensure that the institution meets its obligations to affected third parties, including funding sources, journals, the scientific community, research subjects, and referral sources.

The vice provost/vice chancellor may relieve the person suspected of misconduct from some or all duties at any time during the course of the investigation, but only if it is determined that serious harm to the individual or to others could be caused by the individual's continued performance. Salary payments will continue during any such suspension.

Admission of Misconduct in Research

The procedural stages described above anticipate denial of the allegation by the respondent(s). If the respondent(s) admits to an allegation of misconduct at any stage, the MRO will be informed immediately. Depending upon the procedural stage at which the admission occurs, the respondent(s) should work with the MRO, SCMR, or ad hoc committee to develop a written statement that is fully responsive to the allegation. The statement should also include language attesting that the admission is a true admission, freely given, and not a false one derived from circumstances that may have pressured the respondent(s) into making a false admission. The statement should be signed by the respondent(s) and witnessed by the MRO or chair of the committee involved. Whenever such an admission of misconduct is forthcoming, the MRO or committee involved will exercise due diligence to ascertain that the admission is freely given and that no circumstances are present that might have pressured the respondent(s) into making a false admission. Such admissions will alter some of the specific procedures described in above sections of this document. However, the overall scope and intent of the procedural stages are retained, and the following guidance is provided.

If misconduct in research is admitted to the MRO during the initial assessment, then at the completion of that stage, the MRO will notify the vice provost/vice chancellor and forward the file to the Standing Committee. In such a situation, the role of the SCMR will differ from its usual role: its particular function will be to undertake an independent evaluation of the admission of misconduct, issue a report of its findings, and recommend an appropriate course of action, including sanctions.

The SCMR will:

1. review the materials available and interview the respondent(s);
2. conduct a limited inquiry to determine if the admission by the respondent(s) is freely given; and,

- ascertain whether acts of misconduct other than those admitted by the respondent(s) might have occurred.

The SCMR has the discretion to interview other individuals in conducting its review of the admission of misconduct, including the complainant(s). In completing its Report, the SCMR will include a list of the evidence reviewed, a summary of relevant interviews, its evaluation of the admission of misconduct, and the conclusions of its inquiry.

If misconduct in research is admitted at the SCMR or ad hoc committee stage, then the committee receiving the admission will inform the MRO, who will inform the vice provost/vice chancellor. The committee will then proceed to complete its report of findings in the manner described above for the SCMR. When an admission of misconduct occurs during a committee stage of procedure, that committee's evaluation of the admission of misconduct will be sufficient, with no mandatory need for additional committee review as in the case of admission to the MRO.

Final Determination by University Official

Within fourteen (14) days of receipt of the ad hoc committee's report, the vice provost/vice chancellor shall review the report, render in writing a final determination, including the imposition of sanctions as appropriate, and provide a copy of the determination to the respondent(s). In making this determination, the vice provost/vice chancellor shall not be expected to review independently the evidence considered by the ad hoc committee, but may request clarification or additional information from the ad hoc committee if necessary. The complainant(s) and appropriate third parties will be advised of the final determination.

The respondent(s) has the right to appeal in writing, within fourteen (14) days of receipt of the final determination by the vice provost/vice chancellor. The appeal must be delivered to the vice provost/vice chancellor and to the provost/chancellor for health affairs. If the respondent(s) elects to appeal the determination, the provost/chancellor for health affairs will consider whether the final determination and the sanctions imposed are supported by facts referenced in the ad hoc committee's report. The provost/chancellor for health affairs may request clarification or additional information from previous review bodies if necessary, and the respondent(s) will be afforded an opportunity to meet with the provost/chancellor for health affairs. The chancellor for health affairs will inform the provost of any decisions affecting faculty status. Unless there are extenuating circumstances, the entire appeals process must be completed within thirty (30) days of receipt of the final determination.

If misconduct in research is found and the appropriate sanction is determined to be dismissal from the university, the president and the respondent(s) will be so notified. The respondent(s) will be entitled to a hearing in accordance with existing procedures for dismissal; for faculty members, the procedures are detailed in the Faculty Handbook, Appendix N. If there are no existing procedures applicable to the individual in question, the opportunity for a hearing will be afforded under appropriate related procedures.

Notification of External Research Sponsors

If, on the basis of the allegation inquiry, it is determined that an investigation is warranted, and if the individual accused of misconduct is participating in an externally funded research project, the MRO will advise the appropriate office in the sponsoring entity in writing. In the case of a pending proposal, the MRO will follow the sponsor's guidelines in regard to notification. Notification will occur on or before the date the investigation begins and will include the name of the person(s) involved, the general nature of the allegation, and any identifying application or grant number.

Sponsors will also be notified in writing if at any stage of the inquiry or investigation any of the following conditions exists:

- the health or safety of the public is at risk;
- there is an immediate need to protect human or animal subjects;
- there is an immediate need to protect funds or equipment, e.g., HHS resources or interests are threatened;
- there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
- it is probable that the alleged incident is going to be reported publicly;

6. there is a reasonable indication of possible violations of civil or criminal law--in which case notification within twenty-four (24) hours of obtaining that information is required; or,
7. the institution determines that the research community or public should be informed.

If an investigation is initiated and the ad hoc committee determines at the end of ninety (90) days that it will be unable to complete its investigation in the usual one hundred and twenty (120) days, the sponsor will be so notified in writing. The notification will include an explanation for the delay, an interim progress report, and an estimated date of completion. All documents or reports required by law or regulation to be sent to federal agencies will be forwarded in a timely manner consistent with legal requirements. All sponsors will be advised of the resolution of the investigation at the conclusion of the process. In the interim, administrative action will be taken to protect sponsor funds and to insure that the purposes of the sponsored activity are carried out.

With regard to external sponsors, the Duke University administration will make diligent efforts to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed; they will also undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, have made allegations.

The vice provost will file "assurances of compliance" and other documents as appropriate with sponsoring and regulatory agencies.

Record Retention

All documents related to allegations of misconduct in research will become permanent institutional records and will be maintained in strictest confidence under the direction of the MRO.

Guidelines for Authorship and Authorship Dispute Resolution

As approved by the Academic Council March 20, 2008

INTRODUCTION

Duke University has instituted authorship guidelines and dispute resolution procedures to supplement its policy on Misconduct in Research. A separate but complementary policy was deemed advisable because many allegations of misconduct actually stem from and involve disputes over authorship. Because disputes over authorship rarely involve research misconduct, the Misconduct in Research policy is usually not the appropriate mechanism for resolving such disputes.

Some departments and divisions at the University already provide guidelines for authorship to faculty and students, and expectations are clear on all sides. However, too frequently this does not happen, and bitterness and accusation may result. This policy on authorship, therefore, is designed to fill in the gaps and offer broad guidance across the University.

COMMUNICATING RESPONSIBILITIES AND EXPECTATIONS

Within the academic environment there is often some level of expectation regarding authorship or acknowledgement on the part of those contributing to a work. As a result, it is an appropriate practice to address questions of authorship at the earliest practical stage of a research project. Such communication can clarify roles, spur motivation, and minimize disappointments among the participants. Major questions that should be addressed are the following:

- Who will be named as an author or acknowledged as a contributor if the study is submitted for publication or presentation?
- What will be the order of authorship?
- What are the responsibilities and expectations for each contributor to the study?
- Are there any intellectual property or confidentiality issues involved that may affect publication?

It is important to recognize that roles often change during the course of a project and it may not be possible to appropriately evaluate each author's relative contribution to the work until the manuscript (or presentation) is actually written or even finalized for publication. For this reason, it is important for all involved parties to re-discuss authorship whenever significant changes occur and make it clear to all participants from the start that final decisions about authorship can be extended until the time of submission.

It is also the expectation that the senior investigator(s) associated with a given research project is(are) responsible for anticipating possible disagreements concerning authorship credit and for initiating conversations on the matter before students and other collaborators have invested substantial time on the project.

RECOMMENDED PRINCIPLES OF AUTHORSHIP

A salient fact about authorship is that markedly different traditions of joint authorship exist among different disciplines. Given these variances, specific and universal rules cannot apply. However, a set of general principles should serve as a guide for authorship inclusion across the University.

- Authorship should be restricted to those individuals who have met **each** of the following three criteria: 1) made a significant contribution to the conception and design of the project, or the analysis and interpretation of the data, or other substantial scholarly effort; 2) participated in drafting, reviewing and/or revising the work; and 3) approved the final version for publication.
- Each author should have participated sufficiently in the work to take full responsibility for his or her contributions to the content.
- As a practical matter, with multi-authored publications it is usually important to designate or acknowledge one individual as the Lead Author, who takes responsibility for the integrity of the work as a whole. This Lead Author often also serves as the corresponding author.
- The Lead Author has responsibility for 1) including as co-authors all those who meet the three criteria defined above; and 2) obtaining from all co-authors their agreement to be designated as such.

- The order of authorship should be a joint decision of the co-authors. If a decision cannot be reached, the Lead Author should have final say.
- Acquisition of funding, collection of data, or general supervision of a research group does not justify authorship unless the individual also fulfills the above three criteria.
- Anyone who does not meet the above authorship criteria but who has made other substantial contributions (such as technical help, writing assistance, etc.) should be acknowledged in the final product.
- Honorary or courtesy authorships are inconsistent with the principles of this policy and, as such, are unacceptable.

DISPUTE RESOLUTION

Disputes over authorship are best resolved at the local level by the authors themselves or in consultation with the laboratory chief, chair or head of department(s), or dean, as appropriate.

If resolution at the local level cannot be achieved, the matter can be referred to the Authorship Dispute Board in one of two ways. If the matter is taken to the Authorship Dispute Board with the mutual agreement of all parties, the decision of the Board will be binding on all parties. If the matter is taken to the Authorship Dispute Board without the mutual agreement of all parties, the decision of the Authorship Dispute Board is not binding, but the Board will make a written recommendation that will be provided to all parties of the dispute and can be made public by any of the parties involved.

COMPOSITION OF THE AUTHORSHIP DISPUTE BOARD

The Board shall consist of the following:

- One chair and three faculty members jointly appointed by the provost and the dean of the School of Medicine and approved by the Executive Committee of the Academic Council.
- Two *ex officio* members of the administration, the vice provost for research and the vice dean for research.
- One graduate or professional student appointed by the Graduate and Professional Student Council
- One postdoctoral fellow appointed by the Duke University Postdoctoral Association
- If appropriate, the Board may call upon the expertise of other members of the Duke University faculty.

Any member of the Board involved in attempted resolution of the complaint prior to its consideration by the Authorship Dispute Board will recuse him or herself.

This policy is indebted in part to authorship policies from the following institutions: Harvard University, University of California-San Diego, University of California-San Francisco, University of Pennsylvania, and the Washington University-St. Louis. This policy incorporates authorship principles developed by the International Committee of Medical Journal Editors. More information can be found at <http://www.icmje.org/>.

Principal Investigator Status

(from the Duke University Policy Manual, Policy # VII.180)

August 1997

It is the University policy that only those whom the University has or intends to have an on-going employment or contractual relationship may serve as Principal Investigators or Program Directors for projects, research or otherwise, supported by external funding sources. This policy is implemented as follows:

Campus Components

The status of principal investigators is granted as a matter of privilege to regular rank faculty and to select senior administrative staff. This status is available to faculty on the tenure track and to other regular rank faculty on the Research Professor or Professor of the Practice tracks. In special instances, other members of the University community may request permission to serve as Principal Investigator. Requests for PI status should be sent on behalf of the individual with an approval and endorsement from the relevant department chair (if applicable) to the dean; the request should include an endorsement and an assurance that the department will assume responsibility for the conduct of the grant or contract.

Medical Center Components

The status of principal investigator is granted as a matter of privilege to all faculty in the Medical Center and to select senior administrative staff. This status is available to faculty on tenure tracks I through III and to other regular rank faculty on the Research Professor, Clinical Professor, and Professor of the Practice of tracks. Faculty who are appointed to the non-regular rank tracks IV and V may serve as principal investigators with the approval and endorsement of their departmental chairpersons, who assure the assumption of responsibility for the conduct of the grant should the principal investigator not remain with the University for the duration of the project. In special instances, other members of the Medical Center community may request permission to serve as principal investigator with the approval and endorsement of their departmental chairperson.