

# 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:

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

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

**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: <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>
- 45 CFR 46:  
<https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pid=20180719&n=pt45.1.46&r=PART&ty=HTML>

Investigators must be certified to conduct research with human subjects. For information on the certification process consult <https://campusirb.duke.edu/irb-policies/required-training>.

### *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 (University) is dedicated to teaching, research, and the expansion of knowledge. The University has a mission of knowledge in the service of society, and in that context inventions sometimes result from the research and clinical 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 and Duke University Health System, Inc. 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.

All aspects of these policies shall be implemented in a manner that incentivizes decisions guided by the long view, promotes invention disclosures, ensures prompt reviews of new disclosures, and stimulates wide transition of Duke IP to the marketplace as measured by metrics including licensing transactions and faculty satisfaction.

### **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 Licensing & Ventures. The Provost and Chancellor shall appoint a director of the Office of Licensing & Ventures (OLV) who will be a full-time employee of the University. The director of the Office of Licensing & Ventures 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 or otherwise protectable;
  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. Prepare an annual report to the OLV Board;
  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. Office of Licensing and Policy Board. The OLV Board consists of seven members. Five Board members shall be selected from the faculty and two from the administration. Three of the faculty members shall be selected by the Chancellor of Health Affairs (Chancellor), in consultation with the Dean of the SOM; the Provost shall select two faculty from Campus Schools in consultation with the Deans of those Schools. One of the Campus representatives shall be a faculty member in the Pratt School of Engineering. The Chancellor shall select the SOM administrative representative, and the Provost will select the Campus administrative representative. The Board will be co-Chaired by the Campus and SOM administrative representatives. The director of OLV shall be a non-voting ex-officio member of the Board and the Board shall designate an ex-officio Secretary of the Board. A designated member of the Counsel's Office shall also be a non-voting ex-officio member of the Board. At the discretion of the Chancellor and Provost, a faculty member from the School of Law, with expertise in licensing and patent policy, may be added as an additional Board member. The director of OLV shall report jointly to the Provost and Chancellor, or their designees, who would be the administrative members of the Board. The Board shall:
1. Receive and review the annual report of the Director of the Office of Licensing & Ventures and consult with the Director of the Office of Licensing & Ventures when requested.
  2. Report to the Provost and Chancellor or designees 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 Licensing & Ventures.
  4. Receive requests for interpretations of this policy and, after deliberation, recommend to the President such interpretations as it considers appropriate.
  5. Receive, review and recommend to the Chancellor and Provost the OLV budget as annually submitted by the Director of OLV.
- D. Duke Innovation & Entrepreneurship Initiative
1. The Office of Licensing and Ventures will work with the Duke Innovation & Entrepreneurship (I&E) Initiative and other areas focusing on innovation, to help meet the need for entrepreneurial education. The OLV, Duke I&E and their Boards will work with Deans and Department Chairs to promote a culture of translation across the institution.
  2. Duke strongly welcomes innovation amongst the members of its community that result in patentable inventions. While OLV's resources are targeted towards finalizing patents and ventures, it will also, together with the OLV Board and in conjunction with I&E and other units involved in translation, help define expectations, and provide guidance on ways faculty and students can make their innovations patentable and more attractive to the marketplace.

### **III. Invention Management**

- A. Within three months from submission of a new invention disclosure, OLV will respond to the prospective inventor(s), notifying them of one of the following:
1. The submission is not a valid new invention. The individual(s) who submitted the disclosure may be directed to I&E or to other areas focused on innovation, for help in refining and improving the invention; the prospective inventor(s) will be made aware of what is required of a proper invention.
  2. The submission is of potential value, but it is recommended that it be improved and strengthened, before filing a provisional patent. OLV will work with the inventor(s) to help strengthen the disclosure, and define its proper place in the marketplace, and in so doing better quantify its value. Under this circumstance the inventor(s), OLV and I&E or other entities responsible for translation (upon mutual consent) will work together to strengthen and



position the potential invention, for a subsequent provisional patent. This process may take an extended period that respects the needs of all parties, including the requirements of students to publish their work in a timely manner. The OLV Board may be consulted by the inventor, if desired, to achieve the proper balance between strengthening the invention and the need to publish.

3. If either of the above two options do not apply, OLV will make a statement about whether it is interested in pursuing a provisional patent or not and the timing of the filing or refiling of a provisional patent application to maximize the chances for translational success. If OLV elects not to protect, the invention will be assigned back to the inventor(s), who have the opportunity to pursue the patent(s) as they wish.
- B. After OLV files a provisional patent, it will have six months to inform the inventor if OLV will file additional protection. If OLV chooses not to protect the invention, the invention will be assigned back to the inventor. If the patent is unusually complex, requiring more time for the assign-back decision, such an extension of the above time period must be approved by a majority vote of the OLV Board.
- C. For disclosures or provisional patents that OLV assigns back to the inventor(s), if the inventor(s) chooses to file a patent on their own, that patent must contain claims that are substantially similar with the original invention disclosure and/or the previously filed provisional patent. The OLV Board or its designee will review the consistency between the inventor's patent application and the original disclosure and any provisional patent application. If the inventor's subsequent patent is found to substantially differ from the original disclosure, then the University's assignment shall be null and void and ownership of the invention will revert to the University, with patent costs assumed by the University.
- D. If a license negotiation between OLV and a company proceeds for six months without resolution, unless both sides ask for more time, the OLV Board will intervene, and recommend terms for an equitable outcome, which may include an option to continue to negotiate.
- E. At the regular meetings with the OLV Board, the OLV Director will provide updates on the broad status of inventions as they run through the system, and demonstrate that the desired timelines are being met. Faculty may bring matters of timeliness on the above deadlines to the OLV Board.

#### **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 Licensing & Ventures on the University's Invention Disclosure Form.

##### **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. 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

- 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 (“assign back”) 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, clinical 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 Licensing & Ventures and the inventor as to the determination of equities in an invention shall be resolved by the OLV Board. The decision of the OLV Board 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.

#### **V. Division of Income**

- A. All income derived from inventions falling within Article IV, Section A above shall belong to the inventor.
- B. If inventions that are assigned back by OLV to the inventor shall be patented and/or commercialized by the inventor, then the University and inventor shall enter into an agreement, which shall provide for the inventor to reimburse the University direct expenses, if any, incurred in connection with the patenting and commercialization of the invention.
- C. All income derived from inventions falling within Article IV, 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 Licensing & Ventures 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 inventor's laboratory until, in the discretion of the President after consultation with the Chancellor 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 share in accordance with V.C.2.a.(4) below;
      - (3) ten percent (10 %) thereof to the inventor's department/organizational unit;
      - and
      - (4) thirty percent (30%) thereof to be directed to the school of the inventor's primary appointment.
    - b. income from \$500,000 to \$2,000,000:
      - (1) thirty-three percent (33 %) thereof to the inventor;
      - (2) fifteen percent (15 %) thereof to the inventor's laboratory until, in the

discretion of the President after consultation with the Chancellor 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 V.C.2.b.(4) below;

(3) fifteen percent (15 %) thereof to the inventor's department/organizational unit;

(4) thirty-seven percent (37 %) thereof to the school of the inventor's primary appointment.

c. \$2,000,000 and higher:

(1) twenty-five percent (25 %) thereof to the inventor;

(2) fifteen percent (15 %) thereof to the inventor's laboratory until, in the discretion of the President after consultation with the Chancellor 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 V.C.2.c.(4) below;

(3) fifteen percent (15 %) thereof to the inventor's department/organizational unit;

(4) thirty-five percent (35 %) thereof to the inventor's school;

(5) 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.

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 the inventor's laboratory would have been entitled shall be determined by the school.

b. For purposes of this Article V.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 V.C., the dollar ranges in paragraphs V.C.2.a. (0 to \$500,000), V.C.2.b. (\$500,000 to \$2,000,000), and V.C.2.b. (\$2,000,000 and higher) above, may be periodically adjusted by the OLV Board to reflect changes in the cost-of-living, such adjustment to be effective for the fiscal year beginning that July 1. Any 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 V.C., the net income referred to in paragraphs V.C.2.a. (0 to \$500,000), V.C.2.b. (\$500,000 to \$2,000,000), and V.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 IV, 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 IV, Section E, any royalties received by the University shall be distributed in accordance with Article V, Section C above, unless the contract between the University and the sponsor provides for a different distribution.

F. Income from inventions falling within Article IV, Section F, shall be distributed in accordance with the agreement between the inventor and the University.

## VI. 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.

**VII. Interpretation**

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

**VIII. 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.

**IX. 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.

## **Interpretation of the Policy on Inventions, Patents, and Technology Transfer Reaffirming the Rights of Undergraduate Students**

### PREAMBLE

Duke University has long recognized the important contributions that undergraduate students make to the intellectual community that is the academic foundation of the University. The University hereby confirms its commitment to encourage and nurture the creative and entrepreneurial spirit reflected in the undergraduate students enrolled at Duke in the twenty-first century.

The rights of Duke University undergraduate students in intellectual property have been recognized since the first patent policy was adopted by the University in 1979. Subsequent amendments have reaffirmed those rights. It is the purpose of this Interpretation to reaffirm again the rights of undergraduate students in intellectual property and bring the policy current by recognizing the educational methods and technologies currently available and in use at the University. All references herein to the "Patent Policy" shall be to the revision of the Policy on Inventions, Patents, and Technology Transfer effective July 1, 1996.

Article I. of the Patent Policy: The definition of "students" that are subject to the Patent Policy is confirmed to include undergraduate students.

Article IV. of the Patent Policy ("Ownership of Inventions and Supportive Technology"): The description of invention ownership and rights in Article IV.A., IV.B., and IV.C. is confirmed by the following statements:

Inventions made by undergraduates will generally remain the property of the student, except where the invention is:

- Made through the execution of duties associated with employment at Duke;
- Developed with another inventor who has the duty to assign the invention to Duke. In those instances, ownership will be distributed in a manner proportional to the contribution of each inventor;
- Developed under an external agreement with Duke that explicitly provides for an alternative assignment of inventions.

## **Duke University Policy on Intellectual Property Rights**

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

### **I. General Principles**

- G. 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.
- H. 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.
- I. 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.

1. 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.

- 2. 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.

## **Interpretations of the Policy on Intellectual Property Rights as it Relates to Online Courseware**

### **1. Definitions**

- a. The term internet courseware, as used in this interpretation, refers to any fixed audio/visual work or sound recording that is created for, based on, or adapted or derived from a Duke-sponsored internet distance education course of any type. internet courseware may include recorded lectures, presentation slides, videos and video clips as well as other works to which copyright adheres. Material created for online use by students enrolled in courses that meet for regularly scheduled face-to-face class sessions is not included in this definition unless it is used in an internet course.
- b. The term creator refers to the person or persons, including students, faculty and staff, who would be the owner(s) of copyright in a specific piece of internet courseware through the application of the Copyright Law of the United States (Title 17 of the U.S. Code) if that piece of courseware were not a work made for hire. This interpretation does not have any reference to third-party materials that are incorporated into courseware.

### **2. General principles**

- a. The Duke University Policy on Intellectual Property Rights, including the license allowing all members of the Duke community to make “all traditional, customary or reasonable academic uses” of course content, applies to all Duke community members, whether they are teaching on campus, off campus or online.
- b. This interpretation affirms the general principle of individual ownership expressed in section I(A) of the Policy on IP Rights.
- c. This interpretation affirms that section IV(B) of the IP Rights policy concerning conflicts of interest applies in its entirety to creators of internet courseware.

### **3. Courseware and Clause II(A)3 of the IP Rights Policy**

- a. In the absence of a written agreement, and regardless of whether or not an internet courseware creator receives support for the internet course from the University, section II (A)3 concerning works made for hire shall not apply to that courseware. When a separate, written agreement between a creator and the University that determines the question of ownership has been negotiated, however, that agreement shall have effect.

### **4. Courseware and Clause III(B) of the IP Rights Policy**

- a. The license created by section III(B) of the IP Rights policy for “traditional, customary or reasonable uses” will be deemed to arise in regard to internet courseware in its entirety. In addition, the following special terms apply to this license in internet courseware:
  - i. Any and all revenues generated by courses in which the internet courseware is used, other than direct tuition payments made to the University, will be subject to cost recovery and profit sharing arrangements between the creator(s) and the University, the policy for which will be determined by the Provost in consultation with the Advisory Committee for Online Education.
  - ii. Attribution rights will be respected whenever the internet courseware is used, regardless of whether or not the creator remains a member of the Duke community. Attribution shall be given for all such uses to both the creator(s) and the University.
  - iii. In accordance with section IV(B) of the IP Rights policy concerning conflicts of interest, reuse of the internet courseware on non-Duke platforms or in association with any institution with which the University does not have a formal agreement will be subject to the approval process described therein. This process shall also be used to seek approval whenever a third-party, not subject to the IP Rights Policy and this interpretation, is expected to make a contribution to the courseware. The revenue-

sharing provisions in section 4(a)(i) of this interpretation shall also apply in those situations.

- iv. Revisions of the courseware carried out by anyone other than the creator(s) shall be approved by those creators.

## 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, Sakai, or Box 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. Campus-supported course websites, such as those using Sakai, require passwords for access by default. 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 the director of copyright and scholarly communications or the University Counsel's Office.

## 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 the director of copyright and scholarly communications or the University Counsel's Office.

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### 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.

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### 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

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### 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.

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**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 knowledge that can be of service to Society. Duke believes that it is possible to maintain academic traditions and values that advance the search for truth through free inquiry, while at the same time finding ways to combine its academic perspectives 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, potential conflicts between the missions of academic institutions and industrial sponsors of research. A 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, must be able to recoup and profit from its investments in research by capturing, and often guarding, new knowledge in order to be successful.

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 collaborations have 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.

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 herein. 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. This committee is charged with advising the provost regarding the implementation of these policies, as well as with recommending any 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 research for a private or corporate 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 accept specific research grants or contracts as a condition of employment at the University. However, this policy does not alter

the terms of employment for principal investigators hired by the University to direct or contribute to identified research efforts.

### **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 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 beyond that agreed to in the scope of work defined in the contract or grant.

**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.

#### **A. 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 submission of a publication for more than ninety (90) days, except with the approval of the provost.

#### **B. Preventing Publication**

While having due regard for the sponsor's interests, the university encourages the publication of research results. Therefore, the university will refrain from publication of a sponsor's proprietary information;

however sponsors cannot prevent the use of information necessary to enable complete and accurate publication of the research results. 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. Limitation's on the University's right to publish its research results may only be accepted by the provost 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.

- J. 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. 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 Commitment and Outside Professional Activities

- A. Definition of 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 their 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 commitment.

1. Conflict of Commitment Procedures - Disclosure of Conflict of Commitment: It has long been recognized that consulting, in certain situations, can create in a faculty member a conflict of commitment. The university's policy of restricting a faculty member's consulting to one day a week addresses this issue in part. Among other situations in which faculty may face a conflict of commitment are ownership or management responsibilities by a faculty member in an enterprise outside of the university.

**POLICY:** To assure that the university is informed about arrangements that may pose a conflict of commitment, faculty members shall disclose at least once a year and within 30 days of any change in writing their outside relationships with corporations or other business entities as outlined in the Conflict of Interest Policy (REF). Information disclosed shall include the name of the company, and the nature and scope of the relationship.

## 2. 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.

## *Section II: Administrative Issues*

### **Research Policy Governance at Duke University**

There are at least eight 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 (School of Medicine)
- Office of Licensing & Ventures
- Office of Research Support
- Office of Sponsored Programs
- Office of University Development
- Office of Scientific Integrity

#### **Committees/Councils**

- Conflict of Interest Committee
- Institutional Animal Care and Use Committee
- Institutional Biosafety Committee
- Institutional Review Board (School of Medicine)
- Misconduct in Research Committee
- University Patent Policy Committee
- Research Policy Committee
- 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 president for research. Five faculty members, knowledgeable about research and sponsored projects issues and representing a spectrum of fields, shall be appointed by the vice president 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*

*Revised February 2019*

Duke University strives to foster an atmosphere of honesty and trust in furtherance of the pursuit of knowledge. 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, engage in unacceptable conduct which jeopardizes the reputation of the university and possibly damages their careers and those of colleagues with whom they have collaborated.

Principal investigators have the primary responsibility for ensuring the integrity of the research performed under their supervision. Although colleagues in a cooperative venture bear some measure of individual and mutual responsibility for ensuring the integrity of their joint research, results and publications, 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 contained herein are regularly reviewed and modified, as necessary. Any such modifications will be reviewed and approved through the established university policy review processes.

## I. SCOPE

The following policy and procedures shall apply to all research conducted by faculty, visiting scientists and postdoctoral researchers under the auspices of Duke University. The procedures delineated herein address research misconduct as defined in Section II below.

This policy and procedures shall also be followed for any allegations of research misconduct involving federal funds, regardless of the position of the individual against whom the allegation is made. If no federal funds are involved, allegations of research misconduct on the part of undergraduate, graduate, or medical students may be referred to the applicable School or College for academic review. In these instances, the Deciding Official, in consultation with the appropriate academic leader(s), will determine if this policy and procedures should apply. The Vice Chancellor for Health Affairs is the Deciding Official for the Schools of Medicine, Nursing, and related Centers and Institutes (Medical Center); the Vice President for Research is the Deciding Official for all other Schools, Centers and Institutes.

Similarly, in the absence of federal funding, allegations of research misconduct on the part of staff not holding a research or teaching appointment may be referred for administrative review in accordance with the Staff Handbook. The Deciding Official will determine if this policy should apply.

## II. KEY DEFINITIONS AND CONCEPTS

A. **Allegation** means a disclosure of possible research misconduct through any means of communication to a university official.

B. **Burden of Proof** means that the university has the burden of proof for making a finding of research misconduct. The Respondent has the burden of proof for any affirmative defenses raised, which includes honest error or differences of opinion.

C. **Committee Member** means any individual serving on the Standing Committee on Misconduct in Research or the Investigative Committee.



D. **Confidentiality** means that all those participating or involved in Research Misconduct Proceedings shall not disclose any information regarding the allegations, the proceedings, or the identity of the individuals involved in the proceeding except as necessary to the proper discharge of their employment responsibilities or as required by law.

E. **Deciding Official** means the Vice Chancellor for Health Affairs for the Schools of Medicine, Nursing, and related Centers and Institutes (Medical Center); and the Vice President for Research for all other Schools, Centers and Institutes.

F. **Complainant** means an individual or entity who makes an allegation of research misconduct.

G. **Conflict of Interest** means unresolved personal, professional, or financial conflicts of interest with the Complainant, Respondent, or witnesses which may compromise, or appear to compromise an individual's decisions.

H. **Evidence** means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact. The destruction, absence of, or Respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where it is established by a preponderance of the evidence that the Respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the Respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

I. **Good Faith** as applied to a Complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the Complainant's or witness's position could have based on the information known to the Complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony.

Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping the university meet its responsibilities under this part. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

J. **Inquiry** means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures set forth in Section V of this Policy and applicable federal regulations and external sponsor requirements.

K. **Intentional** means a person acted with the intent that his/her action cause a certain result. In other words, the person undertakes his/her action either intending for, or hoping that, a certain result will follow.

L. **Investigation** means the formal development and examination of a factual record leading to (1) a recommendation not to make a finding of research misconduct or (2) a recommendation for a finding of research misconduct.

M. **Knowingly** means a person acted with awareness that his/her conduct would result in certain consequences. In other words, a person acts knowingly if aware that it is practically certain that his/her conduct will cause a specific result.

N. **Misconduct Review Officer ("MRO")** means the individual who is primarily responsible for the implementation of the policy and procedures herein, including but not limited to assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. The responsibilities of the MRO may be delegated to another individual(s) as approved by the Deciding Official.

O. **Preponderance of the evidence** means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

P. **Recklessly** means a person acted when he/she was aware of a substantial risk that a certain result will occur as a result of action. The risk must be substantial enough that the action represents a gross deviation from what a reasonable person would do.

Q. **Research** means a systematic experiment, study, evaluation or demonstration designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied. For purposes of this Policy, research includes all basic, applied, clinical, translational, and demonstration research in all academic and scholarly fields. Research fields include, but are not limited to, the arts, the sciences, liberal arts, applied sciences, social sciences, the professions and research involving human subjects and animals.

R. **Research Misconduct** means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. The definition does not include honest error or honest differences in interpretations or judgments of data.

- (i) **Fabrication** is making up data or results and recording or reporting them.
- (ii) **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.
- (iii) **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

S. **Research Misconduct Finding** means that:

- (i) There was a significant departure from accepted practices of the relevant research community; and
- (ii) The research misconduct was committed intentionally, or knowingly or recklessly; and
- (iii) The allegation was proven by a preponderance of evidence.

T. **Research Misconduct Proceeding** means any action related to alleged research misconduct, including but not limited to, allegation assessments, inquiries, investigations and administrative appeals.

U. **Research Record** means any data, document, computer file, computer diskette, or any other written or non-written, electronic or hard-copy account or object that reasonably may be expected to provide evidence or information regarding the proposed, performed, reviewed or reported research that constitutes the subject of an allegation of research misconduct. A Research Record may include, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks (physical and electronic), printed or electronic communication;; videos; photographs; films; slides; biologic materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; patient research files; abstracts, theses, oral presentations, internal reports, and any documents and materials provided by or collected from a Respondent in the course of a research misconduct proceeding.

V. **Respondent** means the person(s) against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

W. **Retaliation** means an adverse action taken against a Complainant, witness or committee member by the university or one of its employees or affiliates in response to:

- (i) A good faith allegation of research misconduct; or
- (ii) Good faith cooperation with a research misconduct proceeding.

X. **Sequestration** means that the MRO will, in good faith, take all reasonable and practical steps necessary to obtain custody, inventory, and secure all original evidence (physical and electronic) relevant to the allegation including, but not limited to, research proposals, laboratory records, protocols, images, specimens, machines and equipment, abstracts, theses, presentations, journal articles and correspondence. Research records resulting from research awarded and conducted at Duke University are the property of Duke University, and employees cannot interfere with the university's right to access them.

All available materials relevant to the allegation shall be promptly provided to the MRO. Upon request and where appropriate copies of the sequestered evidence will be provided to the Respondent except for materials not amenable to copying or the Respondent will be given reasonable, supervised access to the sequestered evidence.

In addition to securing records under the control of the Respondent, the MRO may need to sequester records from other individuals, such as co-authors, collaborators, or Complainants. Where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

Y. **Sponsoring Agency** means any federal agency or agencies supporting the research at issue, including federal agencies to which the Respondent(s) have applied seeking support. (Non-federal research sponsors will be provided access to committee reports and institutional findings as provided under the applicable sponsored research agreement).

Z. **Time Limitation** means that this Policy only applies to research misconduct occurring within six (6) years of the date an allegation of research misconduct is received by the university unless:

- (i) The Respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, re-publication or other use for the potential benefit of the Respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized; or
- (ii) The university determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public or research community.

### III. ALLEGATIONS

All members of the Duke University community are expected to report observed, suspected or apparent research misconduct. All allegations of research misconduct from sources inside or outside the university will be considered. An individual should direct an allegation of research misconduct to the MRO, the Office of Audit, Risk & Compliance ("OARC"), the Integrity hotline, or their supervisor. Any individual who receives an allegation of research misconduct shall promptly forward it to the MRO. If an individual is concerned about possible research misconduct or is unsure whether a situation qualifies as research misconduct, he or she may contact OARC or the faculty ombudsperson to discuss the situation informally and confidentially.

Although allegations may be made orally, individuals are encouraged to submit allegations of research misconduct in writing so as to assure a clear understanding of the issues raised. Anonymous allegations are acceptable; however, sufficient detail or corroborating evidence must be provided to determine whether an inquiry should be initiated. Allegations should be based on facts and provide specific information when possible. An allegation should include:

- (i) The name(s) of the Respondent, if known; and
- (ii) A brief description/summary of the circumstances surrounding the allegation(s).

### IV. ORGANIZATIONAL STRUCTURE

A. **The Misconduct Review Officer** is responsible for:

- (i) Receiving and handling allegations of research misconduct in the manner provided for in the procedures set forth herein.
- (ii) Providing necessary administrative support for the relevant Standing Committee on Misconduct in Research and, as necessary, for the Investigation Committee.
- (iii) Coordinating communications with the parties involved in the Research Misconduct proceedings.
- (iv) Maintaining records of all research misconduct allegations, inquiries and investigations in the Research Integrity Office and with OARC. The MRO will provide OARC and the Office of Research Support with an annual summary of the outcome of allegations received.
- (v) Taking appropriate action to sequester relevant data or evidence relating to the allegation and notifying the appropriate offices/individuals at Duke if the health and safety of animals subjects, human subjects, patients or other personnel may be affected.
- (vi) Compliance with all requirements for notification.

## **B. Standing Committee on Misconduct in Research (SCMR)**

Two Standing Committees on Misconduct in Research are established, one for the university and one for the Medical Center, with each having no fewer than three (3) committee members. 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 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. A legal advisor will be appointed by the Deciding Official for each inquiry and will serve as an *ex officio* member throughout the Research Misconduct Proceedings.

If the SCMR needs one or more additional members to conduct an inquiry, such as for timeliness, expertise, or other matters, the Chancellor or Provost, as applicable, may appoint such additional member(s) for the purpose of enabling the timely conduct and conclusion of the applicable inquiry process. Such members shall possess sufficient expertise to enable the SCMR to conduct the inquiry and to evaluate the evidence and issues related to the allegation, and may come from inside or outside the university. Such members will not be involved in the conduct of any other inquiry processes unless appointed by the usual process described above.

### **The SCMR is responsible for:**

- (i) Conducting an inquiry into allegations referred from the MRO;
- (ii) Determining by a preponderance of the evidence whether or not the conduct, if it did occur, would (1) constitute research misconduct, and (2) whether there is sufficient evidence of the alleged misconduct to warrant a full investigation.
- (iii) Recommending to the Deciding Official whether or not the allegation warrants an investigation;
- (iv) Advising the MRO of the need to ensure the health and safety of research participants, if applicable, and to preserve and protect evidence; and,
- (v) Reporting to the MRO, for transmission to the Deciding Official, the outcome of the inquiry in a written report.

## **C. Investigation Committee**

A decision that an investigation is warranted is made by the Deciding Official, on the basis of the SCMR's inquiry into the allegation. If the decision is to proceed with an investigation, the Deciding Official will appoint an Investigation Committee to determine whether misconduct occurred.

The Investigation Committee will consist of at least three (3) members selected to ensure that the investigation is carried out as completely and competently as possible. Each Investigation Committee Member should have no conflicts of interest in the case, be unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the university.

### **The Investigation Committee is responsible for:**

- (i) Evaluating the evidence and testimony of the Respondent, Complainant, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.
- (ii) Pursuing 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 continuing the investigation to completion.
- (iii) Reporting to the MRO, for transmission to the Deciding Official, the outcome of the investigation in a written report.

## **V. MISCONDUCT REVIEW PROCEEDINGS**

Duke University recognizes the importance of addressing allegations of misconduct in research in a timely fashion and with fairness, thoroughness, and confidentiality. Thus, the university has established a process for handling these allegations. This process is intended to meet the requirements of the PHS regulations at 42 C.F.R. Part 93 and NSF regulations at 45 C.F.R. Part 689.

### **A. Assessment**

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.

If, at the conclusion of the assessment, the MRO determines that there are no adequate grounds for the allegation and that no inquiry is warranted, the MRO will notify the Deciding Official in writing the reasons for the decision and if the Deciding Official concurs, will advise the Complainant(s) of the decision.

If the MRO (or Deciding Official) determines that the issues are appropriate for consideration through Research Misconduct Proceedings, the MRO will notify the Deciding Official and the SCMR, and will provide to the SCMR all relevant materials related to the allegation. The MRO will also begin to sequester all related records and other identified evidence.

At the time of, or before the beginning of the inquiry, the MRO shall make a good faith attempt to notify the Respondent(s) in writing of the initiation of the inquiry, including the substance of the research misconduct allegations. Upon receiving notice of the inquiry, the Respondent(s) will assist the MRO with the sequestration process. If the Respondent is not available, sequestration may begin in the Respondent's absence.

### **B. Inquiry by Standing Committee on Misconduct in Research**

The appropriate SCMR shall conduct an inquiry into the allegations referred from the MRO. At least three (3) members of the SCMR who do not have conflicts of interest involving the case will conduct the inquiry.

The MRO will notify the Respondent of the proposed committee membership and the Respondent may submit a written objection to any appointed member of the SCMR within five (5) days. The MRO will solely determine whether to replace the challenged member with a qualified substitute.

The Dean of the applicable school may relieve the Respondent(s) from some or all duties at any time during the course of the inquiry and/or investigation. The Respondent(s) may be placed on administrative leave if the Dean determines this to be appropriate. In that case, salary payments will continue through the inquiry phase unless determined otherwise by the Dean. The Dean will determine whether salary payments should be continued during the investigation. The Dean may also hold the Respondent's dossier for tenure and/or promotion through the conclusion of the Research Misconduct Proceedings.

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.

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 SCMR 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 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:

- (i) the names and positions of the Respondent(s);
- (ii) a description of the allegations of research misconduct;
- (iii) any external support involved, including, for example, grant numbers, grant applications, contracts, and publications listing external support;
- (iv) the basis for recommending that the alleged actions do or do not warrant an investigation; and,
- (v) any comments on the report by the Respondent(s).

Unless circumstances require, the inquiry shall be concluded within sixty (60) calendar days of initiation, inclusive of the time provided to the respondent to comment on the inquiry report. If the report is not submitted within that period, the report will document the reasons for the delay.

The report will be provided to the Respondent(s) for comment. Any comments from the Respondent must be provided to the MRO within fourteen (14) calendar days of receipt of the inquiry report; these comments shall be appended to the report.

If the SCMR determines that an investigation is not warranted, the report will detail the reasons for the determination.

The MRO will promptly provide a copy of the inquiry report to the Deciding Official, and will advise the Complainant(s) of the findings.

### **C. Investigation Committee**

If an investigation is warranted, such investigation shall begin within 30 days of the determination. The Deciding Official will appoint an Investigation Committee to determine whether misconduct did or did not occur. The MRO will promptly provide to the Investigation Committee the inquiry report and other relevant information assembled by the SCMR.

The Respondent(s) shall be notified in writing of the allegations to be investigated within 30 days of the determination that an investigation is warranted. The Respondent(s) shall also receive written notice of any new allegations within a reasonable time after the Investigation Committee makes a determination to pursue allegations not addressed in the inquiry or in the initial notice of the investigation.

Throughout the investigation, Respondent has the right to legal counsel at his/her own expense; such legal counsel may be present and confer with their client during interviews, but may not otherwise participate or disrupt the proceedings.

If the investigation 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. The Deciding Official will determine if review of the additional Respondents will be conducted by the current Investigation Committee or through a new inquiry or Investigation Committee. The point at which the new information is received, as well as its relation to the original allegation, will be considered in decisions as to whether the allegation is treated as a separate issue or as part of the current investigation.

The university shall take reasonable steps to ensure an impartial and unbiased research misconduct proceeding: those conducting the investigation shall be selected on the basis of their experience pertinent to the matter and, prior to selection, potential committee members shall be screened for any conflicts of interest with the Respondent(s), Complainant(s), potential witnesses, or others involved in the matter. Any actual conflict will disqualify the individual member from selection for service on the Investigation Committee. Prior to the beginning of the investigation, The MRO shall provide the Respondent(s) in writing with the proposed investigation committee membership. The Respondent(s) may object to any proposed member of the committee based on a conflict of interest within five (5) days of receiving notification of the potential committee membership. The Deciding Official makes the final determination whether an actual conflict exists.

The MRO shall provide the appropriate office of the sponsoring agency written notice of the investigation. Such notice will occur on or before the date the investigation begins and shall include the name of the person(s) involved, the title/number of the grant contract, and the inquiry report. The MRO will keep the sponsor agency informed of the progress of the research misconduct proceedings.

The Investigation Committee is authorized to obtain expert consultation and to secure any necessary documentation or data, and all personnel are obliged to cooperate.

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. If a party chooses not to participate, the Investigation Committee may proceed in their absence. A copy of the audio file or transcript from interviews will be provided to the interviewed party for comment and written comments received from the interviewed party will be included in the record.

The Investigation Committee will prepare its final report within one hundred and twenty (120) calendar days of initiation of the investigation unless there are extenuating circumstances. When required, a sponsor will be asked by the MRO for an extension of the time needed to conduct the investigation. In developing its findings, the Investigation Committee shall act by simple majority vote of the committee members, based upon the preponderance of evidence.

The Investigation 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). 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, but will not be provided with committee minutes, summaries or notes prepared by the committee or individual committee members, or other deliberative documents. The Respondent(s) will have thirty (30) calendar days to provide written comments on the draft report to the MRO. These comments will be considered by the Investigation Committee in its preparation of its final report, to which such comments will be attached.

The final report of the investigation will include the following:

- (i) a list of the committee members;
- (ii) a description of the nature of the allegations of research misconduct, including identification of the Respondent(s);
- (iii) a description of how and from whom information was obtained;
- (iv) a list the individuals interviewed by the committee;
- (v) a description of the related external research support, including, for example, grant numbers, grant applications, contracts, and publications listing sponsored support;
- (vi) a description of the specific allegations of research misconduct considered in the investigation;
- (vii) a copy of the university policy and procedures under which the investigation was conducted;
- (viii) identification and summary of the research records and evidence reviewed during the investigation.
- (ix) for each separate allegation of research misconduct identified during the investigation, provide a finding as to whether or not the conduct was a significant departure from accepted practices of the relevant research community, and if it was:
  - (a) identify whether the research misconduct was falsification, fabrication or plagiarism, and if it was intentional, knowingly or in reckless disregard;
  - (b) summarize the evidence supporting the finding and discussion of the merits of any explanation by the Respondent(s) and any evidence that rebuts the Respondent's explanations.
  - (c) identify the specific research support;
  - (d) identify any publications, known at the time of the Investigation report, which need correction or retraction;
  - (e) identify the person(s) responsible for the research misconduct; and
- (x) any written comments made by the Respondent(s) on the draft investigation report.

The report will be addressed and delivered to the Deciding Official. A copy of the final report will be provided to the MRO and Respondent(s), and the Complainant(s) will be informed of the Deciding Official's findings by the MRO.

The factual findings of the Investigation Committee shall be conclusive and binding on any later proceeding convened for other purposes, e.g. grievance to the Faculty Hearing Committee related to sanctions imposed by the Deciding Official or others.

If, on the basis of the investigation, an individual is found to have engaged in research misconduct, the Investigation Committee may request a meeting with the Deciding Official to make its recommendations on appropriate follow-up. Follow-up could include recommended sanctions as well as steps to ensure that the university meets its obligations to affected third parties, including funding sources, journals, the scientific community, research subjects, and referral sources.

## VI. NOTIFICATIONS

### A. Notice to Respondent(s)

- (i) **Initiation of Inquiry:** Prior to, or at the beginning of an inquiry, the MRO will provide the Respondent(s) with written notification of the inquiry, including the substance of the research misconduct allegations. If the inquiry subsequently identifies additional respondents, they shall be promptly notified in writing.
- (ii) **Results of Inquiry:** Upon conclusion of the inquiry, the university will provide the Respondent(s) with the inquiry report, providing opportunity for comment.
- (iii) **Initiation of Investigation:** Within thirty (30) days of the determination that an investigation is warranted, the university will notify the Respondent(s) in writing of the allegations to be investigated. The Respondent(s) will also receive written notification of any new allegation within a reasonable time after the Investigation Committee makes a determination to pursue allegations not addressed in the inquiry or in the initial notice of the investigation.
- (iv) **Proposed Investigation Committee Membership:** Prior to the beginning of the investigation, the MRO will provide the Respondent(s) with written notification of the proposed investigation committee membership.
- (v) **Draft Investigation Report:** The Investigation 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). 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, but will not be provided with committee minutes, summaries or notes prepared by the committee or individual committee members, or other deliberative documents.

### B. Notice to Complainant(s)

- (i) **No Adequate Grounds:** During the Assessment Stage, if the MRO and Deciding Official concur that there are no adequate grounds for the allegations of research misconduct, the MRO will advise the Complainant(s) of the decision.
- (ii) **Following Inquiry Report:** Following the SCMR's completion of the inquiry report, the MRO will advise the Complainant(s) of the findings.
- (iii) **Following Final Investigation Report:** Following the completion of the Investigation Committee's Final Report, the MRO will inform the Complainant of the Deciding Official's findings, excluding any recommendations for disciplinary action.

### C. Notice to Sponsoring Agencies

- (i) **Decision to Open an Investigation:** On or before the date on which the investigation begins, the university will provide the appropriate office of the sponsoring agency with the SCMR's inquiry report and written determination that an investigation is warranted.



- (ii) **NIH:** When the university finds, learns, or suspects that falsified, fabricated, or plagiarized information has affected the integrity of NIH-supported research, including but not limited to, applications for funding and progress reports, or published research or research products supported by NIH funds, the university will immediately notify the NIH Office of Extramural Research – Research Integrity (OER-RI) in a manner consistent with the ORI confidentiality regulations.
- (iii) **After the Investigation:** Following the conclusion of the Research Misconduct Proceedings, the university will provide the appropriate office of the sponsoring agency: (1) a copy of the final investigation report, all attachments, and any appeals; (2) a statement of whether the university found research misconduct and, if so, who committed it; (3) a statement of whether the university accepts the findings in the investigation report; and (4) a description of any pending or completed administrative actions against the Respondent.
- (iv) **Non-federal sponsors:** Notification, reports and/or institutional findings will be provided to non-federal sponsors as required under the terms of the sponsored research agreement.

#### **D. Exigent Circumstances:**

Throughout the Research Misconduct Proceedings, the MRO will monitor the situation to determine if there is any threat of harm to public health, sponsored funds, equipment, the integrity of the externally sponsored research process or university resources, personnel, students or trainees. At any time, in consultation with the Deciding Official, the university will immediately notify the appropriate office of the sponsoring agency if it has reason to believe that any of the following conditions exist:

- (i) the health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- (ii) sponsor agency resources or interests are threatened;
- (iii) research activities should be suspended;
- (iv) a reasonable indication of possible violations of civil or criminal law;
- (v) federal action is required to protect the interests of those involved with the research misconduct proceeding;
- (vi) a likelihood that the alleged incident is about to be reported publicly; or
- (vii) the research community or public should be informed.

At any stage of the case, the Deciding Official will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which potentially falsified, fabricated or plagiarized reports may have been published, collaborators of the Respondent(s) in the work, or other concerned parties should be notified.

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 will be maintained securely and confidentially and will not be disclosed, except to those who need to know to carry out the research misconduct proceeding.

## **VI. FINAL DISPOSITION**

### **A. Admission of Research Misconduct**

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 Investigation Committee to develop a written statement that is fully responsive to the allegation. The statement should 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 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 sections of this policy. 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 Deciding Official and forward the file to the SCMR. 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:

- (i) review the materials available and interview the Respondent(s);
- (ii) conduct a limited inquiry to determine if the admission by the Respondent(s) is freely given; and,
- (iii) 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 inquiry or investigation stage, then the committee receiving the admission will inform the MRO, who will inform the Deciding Official. 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.

## **B. Deciding Official Determination**

The Deciding Official will review the investigation report, render in writing a final determination, including the imposition of sanctions as appropriate, and provide a copy of the determination to the MRO, who will transmit it to the Respondent(s). 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) calendar days of receipt of the final determination by the Deciding Official. The appeal must be delivered to the Deciding Official and to the Chancellor for Health Affairs (for the Medical Center) or Provost (all other units). If the Respondent(s) elects to appeal the determination, the Provost or Chancellor for Health Affairs will consider whether the final determination and the sanctions imposed are supported by facts referenced in the Investigation Committee's report.

The Provost or Chancellor for Health Affairs may request clarification or additional information. 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) calendar 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. If there are no existing procedures applicable to the individual in question, the opportunity for a hearing will be afforded under appropriate related procedures.

## **C. Protection from Retaliation**

The university is committed to and strongly believes in the importance of protecting all individuals from retaliation for his/her good faith activities in cooperation with, or initiation of, Research Misconduct Proceedings. The university will not tolerate acts of retaliation, actual or perceived, against individuals participating in Research Misconduct Proceedings. If any person involved in a Research Misconduct Proceeding feels that have been adversely affected by retaliation, they should notify the MRO, OARC, or their supervisor immediately.

#### **D. Restoring Reputation**

With regard to external sponsors, the Duke University administration may undertake appropriate efforts to restore the reputations of persons alleged to have engaged in misconduct when the totality of the circumstances warrant; they will also undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, have made allegations.

#### **E. Assurances & Record Retention**

The Vice President for Research will file “assurances of compliance” and other documents as appropriate with sponsoring and regulatory agencies.

All documents related to allegations of misconduct in research will be maintained by the MRO for at least seven (7) years after completion of the Research Misconduct Proceeding, including any proceedings conducted by a sponsor.

## **Faculty Communication to External Sponsors on Administrative Issues**

The University encourages as-needed communication between faculty and external sponsor program officials on matters related to science and research. When sponsoring entities – federal, foundation, or industry – communicate funding, procedural, or final budget decisions, any appeal of those decisions must be made through an authorized Duke official. Faculty and staff are not authorized to contact sponsors directly about administrative matters. If a faculty member wishes to appeal a sponsor decision, the faculty should alert the grant manager who will take the request and justification for the appeal to the University’s liaison to federal sponsors, who will manage the related interaction as appropriate. If Duke agrees to process the appeal, the faculty member and the grant manager will be notified by the liaison as soon as the sponsor provides Duke with a decision.

## 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 president for research and the vice dean for basic science.
- 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**

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: requests for faculty and other members appointed to university institutes and centers should be sent with an approval and endorsement from the relevant institute director and center director (if applicable) to the vice provost for interdisciplinary studies. The request should include an endorsement and an assurance that the department or institute/center will assume responsibility for the conduct of the grant or contract.

### **School of Medicine Components**

The status of principal investigator is granted as a matter of privilege to all regular rank faculty in the School of Medicine. In special instances, non-regular rank faculty, senior administrators and other members of the School of Medicine community may request permission to serve as principal investigator with the approval and endorsement of their departmental chairperson. In granting such approval, the chairperson assures that the department will assume responsibility for the conduct of the grant should the principal investigator not remain with the University for the duration of the project.

## **Policy on Open Access to Research**

*Adopted by Academic Council, 18 March 2010*

The Faculty of Duke University is committed to disseminating the fruits of its research and scholarship as widely as possible. In addition to the public benefit of such dissemination, this policy is intended to serve faculty interests by promoting greater reach and impact for articles, simplifying authors' retention of distribution rights, and aiding preservation. In keeping with these commitments, the Faculty adopts the following policy.

Each Faculty member grants to Duke University permission to make available his or her scholarly articles and to reproduce and distribute those articles for the purpose of open dissemination. In legal terms, each Faculty member grants to Duke University a nonexclusive, irrevocable, royalty-free, worldwide license to exercise any and all rights under copyright relating to each of his or her scholarly articles, in any medium, and to authorize others to do so, provided that the articles are not sold. The Duke faculty author remains the copyright owner unless that author chooses to transfer the copyright to a publisher.

The policy will apply to all scholarly articles authored or co-authored while the person is a member of the Faculty except for any articles completed before the adoption of this policy and any articles for which the Faculty member entered into an incompatible licensing or assignment agreement before the adoption of this policy. The Provost or Provost's designate will waive application of the license for a particular article or delay access for a specified period of time upon written request by a Faculty member.

To assist the University in distributing the scholarly articles, each faculty member will make available, as of the date of publication or upon request, an electronic copy of the final author's version of the article at no charge to a designated representative of the Provost's Office in an appropriate format (such as PDF) specified by the Provost's Office. The Provost's Office will make the article available to the public in Duke's open-access repository. In cases where the Duke license has been waived or an embargo period has been mutually agreed, the article may be archived in a Duke repository without open access for the period of the embargo, or permanently in cases of waiver.

The Office of the Provost, in consultation with the Executive Committee of the Academic Council, will be responsible for interpreting this policy, resolving disputes concerning its interpretation and application, and recommending changes to the Faculty from time to time.

The Faculty calls upon the Library Council and Duke University Libraries to develop and monitor a plan for a service or mechanism that would render compliance with the policy as convenient for the faculty as possible.

The policy and service model will be reviewed after three years and a report presented to the Faculty.

For more information on the implementation of this policy, see <http://library.duke.edu/openaccess/> or contact the director of copyright and scholarly communications at Duke University Libraries.