Columbia College Chicago
Policy to Protect Human Subjects and Animals

Columbia College Chicago is an institution that engages in or may engage in research involving human participants and animals. The *personnel* who undertake research at Columbia may include faculty, staff or students. The *form* of the research may vary widely depending upon the discipline(s) in which the research occurs. The *participants or subjects under study* may include students taking Columbia classes, members of the public, staff or faculty of Columbia.

Research activities at Columbia could involve (but are not limited to) the following: Faculty, staff and students undertaking research that involves human participants or animals by conducting experiments, written or oral surveys, interviews, or the audio or visual depicting of a human subject. (These research activities, if occurring as part of a class assignment, may also come under the jurisdiction of the Institutional Review Board [IRB]).

The United States Department of Health and Human Services defines *research* as, "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities."

It is the policy of Columbia College, however, that all educational activities and institutional research involving human subjects be conducted in accordance with the ethical principles outlined in Section B.

B. Statement of Institutional Policy

1. In accordance with the Mission of this institution, Columbia College Chicago acknowledges and accepts its responsibilities to protect the rights and welfare of human research participants and to protect animal welfare. The College has established a policy for the protection of human research subjects which is applicable to all research involving human subjects, and all other activities which involve such research and:

a. Is sponsored by the College, or
b. Is conducted by or under the direction of any employee of the College in connection with his or her College responsibilities, and has received authorization from the College.
c. Is conducted by or under the direction of any individual using property or facilities of the College, and has received authorization from the College.
d. Involves the use of the College's nonpublic information to identify or contact human research subjects or prospective subjects.

An employee of the College is considered to be any full time faculty or staff member. Registered students of the College carrying out class assignments, or fulfilling the requirements of their degree programs, are agents of the College.

3. Institutional Responsibilities

a. The College will provide administrative support for the activities of the IRB.
b. The College will make available a meeting place and sufficient staff to support the IRB's review and recordkeeping duties.
c. The College will create and abide by a statement of principles governing the College in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the College, regardless of whether the research is subject to Federal regulation. This may include an existing code, declaration, or statement of ethical principles, or a statement formulated by the College. See #4.

4. Statement of Ethical Principles

Columbia College Chicago is committed to academic freedom and the pursuit of knowledge. Research will not be forbidden because it is innovative, unorthodox, sensitive, or otherwise extraordinary or compelling. The College protects the rights of faculty, staff, and students to conduct research with human and animal subjects when that research has been reviewed and approved by the Institutional Review Board.

Anyone involved in conducting research has an obligation to respect the dignity and integrity of the persons being studied, including their right not to be the subject of research. Researchers who promise confidentiality are responsible for maintaining it and for informing subjects of their ability to meet that responsibility. Research procedures should minimize the risk of harm and maximize the possible benefits to the subject and to society. Subjects should be selected for reasons directly related to the issue being studied, not because of their easy availability or their manipulability. Researchers must exercise special care when the subjects of research are vulnerable to harm because they cannot understand the risks of a study or because they are not in a position to refuse to participate in the research. Potential subjects should have the opportunity and means to decide freely whether to participate.

All research conducted by Columbia College Chicago faculty, students, and staff, at Columbia or at other institutions and research sites, must conform to these ethical principles. Research that proceeds in violation of this policy is subject to disciplinary action by the appropriate college official, typically the Provost or his or her designee.

C. Procedures

1. The College shall establish and maintain an Institutional Review Board, in accordance with College policy for the protection of research participants or subjects, which directs the process for the review of research covered in this policy.

2. All research involving the use of human subjects or animals, as described in Section B above, shall be submitted for review in accordance with the process established by the IRB (Section G).

3. In carrying out its charge, the IRB will review research designs involving human or animal subjects, giving proper attention to:

a. The potential risks to the subjects,
b. The anticipated benefits to the subjects, the profession, and society at large,
c. Description of the research methodologies and procedures to be used, and
d. The informed consent process to be employed, including where applicable, signed consent.

D. The Institutional Review Board (IRB)

1. The IRB is responsible for reviewing and approving all research with human and animal subjects conducted by faculty, staff, and students of Columbia College Chicago, when conducted as part of their work or study at Columbia. The IRB will review proposed studies to ensure that the dignity, rights, safety, and well-being of all actual and potential research participants are protected; and examine the method in which informed consent is to be sought.

2. Objectives:

a. To maintain ethical standards of practice
b. To protect subjects of research from harm or exploitation
c. To provide reassurance to others that appropriate research activity is being carried out
d. To ensure appropriate consent procedures are followed

3. The IRB will consist of seven (7) voting members, appointed by the Provost of the College or his/her designee. The Provost also will appoint the Chairperson of the committee. The membership will include no less than one (1) member with a scientific background. Three (3) members will be chosen from the full time faculty. Three (3) members will be selected from staff and administration. One (1) member will be chosen from outside Columbia College Chicago and maintain no formal affiliation with the College. The Director of Corporate, Foundation and Government Relations will serve as an ex-officio and non-voting member. Members serve for three-year terms, which shall be staggered. These terms are renewable.

4. The IRB will plan to meet monthly to conduct the timely review of proposals with human subjects or dealing with animal research. These meetings will not be held more than monthly unless a special request is made to the Chairperson of the IRB and she or he approves of the request. Such a request may be warranted in the case of an impending student thesis deadline, grant application, or external review. A quorum will consist of four (4) voting members. Actions of the IRB shall be directed by a majority of those members present and voting.

5. Discovery of unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB, should be reported by the person(s) making the discovery to the Chairperson of the IRB.

E. Responsibilities of the IRB

1. The IRB shall review ethical implications of all research involving humans and animals carried out by college activity to ensure that:
   - The proposed study is valid scientifically or conforms to the accepted standards and practices of the research discipline in which it is framed, and is justifiable in terms of its possible benefits compared with any risk of inconvenience or harm;
   - Adequate steps have been taken so that physical or psychological harm does not occur;
   - The confidentiality of all personal information is ensured and privacy maintained;
   - Consent is truly valid (informed and given without any form of duress).

2. Receive proposals for inquiries, investigations, research, and procedures and shall, after review, allow, refer back, or disallow such proposals, specifying where necessary any conditions.

3. Make available application forms, guidelines and background documentation.

4. Advise on effective preparation of applications

F. Reporting Responsibilities of the IRB

1. The IRB shall maintain adequate records of its activities, in the Office of Academic Research, in accordance with College policies. Records will be maintained for a period of seven (7) years.
2. The IRB shall have the responsibility to respond to written complaints about the treatment of human subjects and animals in research projects approved by the committee.
3. The IRB will report within two (2) business days to the appropriate College official (Provost or Associate Provost) knowledge of:
   a. Any serious or continuing noncompliance with the requirements of the IRB,
   b. Any termination of IRB approval,
   c. Injuries to human or animal research subjects,
   d. Unanticipated problems involving risks to subjects or others.
4. The IRB should be transparent in all its work by:
   a. Recording minutes that are accessible to the community
   b. Reporting annually to the Provost on studies approved/not approved.

G. Reporting Responsibilities of Research Investigators:

1. Application for IRB review must include:
   a. Name of the study and principal investigator;
   b. Details of any outside organization participation;
   c. Funding;
   d. An abstract of the study;
   e. Details of participants;
   f. Copies of consent forms.
2. Information should be provided to all potential participants and should include:
   a. An invitation to participate

   b. Explanation of how the individual has been selected
   c. Procedures/process of the study
   d. Explanation of the participant's role in the study;
   e. Details of any possible discomfort, stress, or inconvenience that participation in the study may cause;
   f. Information on confidentiality
   g. Assurance of a debriefing
   h. Information on the right to withdraw from participating
3. Research investigators shall report promptly to the IRB all proposed significant changes in research activity reviewed and approved by the IRB, as it relates to the treatment of human subjects and animals. Significant changes in research activities include alterations in research design, data collection procedures, or consent forms that were previously reviewed and approved by the IRB.
4. Any such changes will not be initiated without written IRB approval except where necessary to eliminate immediate hazards to human research subjects or animals. The IRB will evaluate these changes and respond to the researcher in a prompt and timely manner.
5. Principal Investigator (PI) shall report promptly to the IRB any unanticipated problems involving risks or injury to human research subjects or animals.
6. Principal Investigator (PI) shall maintain complete records of research activities involving human research subjects.
7. Researchers shall follow the professional and ethical standards of their discipline and profession.
8. Consent forms must be used when the study aims to gather personal or other sensitive data about individuals. Without informed consent a participant must not be allowed to participate in the study.

H. Informed Consent Requirements

Columbia College Chicago adheres to the requirements set forth below for seeking informed consent from research subjects. Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information given to the subject or the representative will be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. The IRB will provide a consent form template.

In seeking informed consent, the following information will be provided to each subject:

(1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a

description of the procedures to be followed, and identification of any procedures which are experimental;

(2) a description of any reasonably foreseeable risks or discomforts to the subject;

(3) a description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, the following information also will be provided to each subject:

(1) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) any additional costs to the subject that may result from participation in the research;

(4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) the approximate number of subjects involved in the study.

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs; and

(2) the research could not practicably be carried out without the waiver or alteration.

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects;

(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) the research could not practicably be carried out without the waiver or alteration; and

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

I. Process and Timeline for Review

The IRB will review applications once per month from September to May of each academic year and by special arrangement during June, July and August.

The Principal Investigator (PI) will complete the application form online and submit to the Office of Academic Research by the 1st of the month or nearest business day after the 1st (September-May)

Completed applications will be distributed to all IRB committee members for review on the 2nd of the month or nearest business day after the 2nd

The IRB will meet to discuss applications, with PI attending for discussion portion of the meeting, and make decisions the third week of each month (September-May).
The IRB will initiate a written response to the PI within five (5) business days, excluding College holidays and vacation periods. The IRB will:

1. Fully approve the research as submitted or,

2. Require alteration in some aspect of the application which will be resubmitted in writing for the IRB Chairperson to review or,
3. Require significant revision of the application, which will be resubmitted to the full committee.

Decisions made by the IRB committee are final and binding and may only be appealed to the full committee.

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