

March 16, 2012

**COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD
GUIDANCE
STUDENTS AS RESEARCHERS**

I. SCOPE:

This Guidance applies to all research involving humans conducted by students at Columbia University (“Columbia”) and provides supplemental information to the “Students as Researchers” Policy to facilitate human research conducted by students. This guidance provides practical information that will facilitate the submission of student research proposals to the Columbia Institutional Review Board (IRB).

II. EFFECTIVE DATE:

III. BACKGROUND:

Recognizing the time constraints imposed on student research projects that must be started and completed within a single semester, the IRB will make every effort to work with faculty and students to process proposals promptly. However, instructors must plan for and allow adequate time for the review process. The amount of time required for IRB review is dependent on the particular human subject issues raised by the proposed research and the completeness (i.e., quality and inclusion of appropriate details to allow for regulatory determinations) of the protocol that is submitted. The later in the term a proposal is received, the more difficult it will be to accomplish the review in time for the project to be completed during the current semester. It is strongly recommended that proposals be submitted to the IRB within the first three weeks of the semester for projects that must be completed during the same semester.

The Columbia IRB has created a simplified IRB submission process for students to help address the above mentioned challenges.

IV. Selection of Topic to be Investigated

Students engaged in the process of learning research techniques understandably want to focus on compelling or real-life issues. In the process of reviewing student research, however, the IRB has found topics and proposed studies that raise concerns for the well-being of the subjects and students themselves. Projects collecting data about illegal activities, those which could cause emotional distress in the subjects, those which would place the subjects at risk if confidentiality were breached, and those with children as subjects are some examples of projects that need to be constructed with special care.

Policies and guidance that may provide insights for addressing special considerations during development of a protocol are available on the IRB websites. IRB staff members are available

for consultation and can provide guidance in constructing a protocol that involves sensitive issues so that human subject protection requirements may be met; however, protocols that include the afore-mentioned elements may require additional review time.

A. Research with Protected Health Information

There are federal regulations (i.e., HIPAA) and institutional policies that govern the access or use of protected health information (PHI; e.g., identifiable medical records/information or biological samples). Any research using PHI needs IRB approval.

B. International Research

If the research will be conducted in another country, the student and IRB must consider additional issues before approval can be granted. The student should review the International Research sections (both Submission Materials and Review of Research Involving International Sites) of the IRB Standard Operating Procedures at: <http://www.cumc.columbia.edu/dept/irb/policies/index.html>.

The IRB will also need more time to acquire and confirm information about the local setting, such as local norms/customs, laws, and possibly obtain approval from a local ethics committee and/or institution. The IRB encourages students and faculty members to consult with the IRB staff while they are designing an international research study.

The Office for Human Research Protections (OHRP; in the U.S. Department of Health and Human Services) provides a registry of laws and standards pertaining to the ethical conduct of human research in many foreign countries. The registry can be found at: <http://www.hhs.gov/ohrp/international/index.html>.

C. Research with Other Institutions

Any research with another institution requires the approval of appropriate officials within that institution and their IRB/ethics committee, if applicable. Such approvals should be obtained and submitted to the Columbia IRB. Researchers may consult with the Columbia IRB regarding necessary approvals.

D. Research in the New York City Public School System

Any research activity involving humans (including activities not covered by Regulations) conducted in the New York City Public School system will require review by the Columbia IRB and the New York City Department of Education IRB.

V. Submission of a Research Study for IRB Review

The IRB receives applications for review via an electronic web-based system called RASCAL. The Columbia IRB has introduced a new abbreviated submission process for research conducted by students. Some RASCAL fields that provide necessary information for IRB review or tracking of protocols will still need to be completed. However, many fields in the RASCAL IRB module will not be need to be completed for research conducted by students. Therefore, students should rely on this guidance, rather than the Instructions and Help Screens in RASCAL for the preparation of their submission.

The rationale for implementation of this abbreviated submission process is that the Columbia IRB recognizes that students have a limited time to prepare and conduct their research study and are generally not familiar with the RASCAL IRB module. As a result, the Columbia IRB provides a process that will facilitate the submission and review of student research proposals by the IRB. The Columbia IRB provides template consent language on its websites that should be relied upon for drafting informed consent documents.

Abbreviated Submission Process in the RASCAL IRB Module for Research Conducted by Students

- A. General Information screen: Complete all fields.

- B. Personnel screen: Add all individuals who will be involved in the conduct of the study. The qualifications of the Principal Investigator must be consistent with the [institutional requirements](#). The student(s) who will conduct the research should be listed as “Student” in the Study Personnel section in RASCAL (this is done by selecting “Student” on the drop-down list for “Role”).

- C. Research screen:
 - 1. Enter Research Questions/Hypothesis(es);
 - 2. Enter Scientific Abstract;
 - 3. Enter Lay Abstract;
 - 4. Study Description field: Enter the following statements:
 - “This is a study that will be conducted by a student(s) *[provide the name(s) of the student(s)]*. Please see the attached protocol for scientific and procedural details.”
 - Elements described in item J below that are not in the separate protocol (description of the project) should also be added to the Study Description.

- D. Funding screen: Complete all fields.

- E. Location screen: Complete all fields.

- F. Subjects screen: Complete all fields (i.e., # and demographics of subjects to be enrolled). In the Subjects Justification field, state the total number to be accrued for the study and the number of sites. If the research involves the request for a waiver of documentation of consent or a waiver of consent, justification should be provided in the ‘Consent Form Waiver/Alteration Request’ field.

- G. Child Involvement screens: Complete, if children are included among subjects.

- H. Human Specimen screen: Complete, if biological samples will be involved.

- I. Complete and attach any applicable Hazmat appendices, if applicable.

- J. Attach protocol that includes the following information:
 - 1. Hypothesis and summary of abstract;

2. Research Methodology/Research Procedures;
 3. Identification of specific data that will be collected;
 4. Description of how data will be identified (e.g., identifiable, coded, de-identified, anonymous; see [IRB Terminology Related to Tissue or Data Collection](#)), maintained and stored (paper, electronic, audio-tape, video, other), and plans for maintaining confidentiality of identifiable data;
 5. Plans for monitoring data and safety, if applicable;
 6. Description procedures for recruitment of subjects (e.g., in person, letter, phone call, access to their information) and what recruitment materials will be used (e.g., flyers, letters, etc.);
 7. Description of the informed consent process.
- K. Attach applicable consent documents, e.g., consent, assent, parent permission forms, and information sheets. The Columbia IRB recommends that informed consent documents are created using the RASCAL “Consent Form Builder” as this tool provides IRB-approved consent statements.
- L. Complete and attach any applicable HIPAA forms. The Columbia IRB requires that researchers utilize the HIPAA Module in RASCAL to create HIPAA forms, if Protected Health Information will be collected during the study.
- M. Attach all study instruments and supporting documents:
1. recruitment flyers, website or print advertisements;
 2. questionnaires, surveys, and/or interview guides;
 3. any required approvals from other institutions, IRBs, or ethics committees.

Columbia IRB Websites

CU-MS IRB: <http://www.columbia.edu/cu/irb/>

CUMC IRB: <http://www.cumc.columbia.edu/dept/irb/>

Appendix A: **45 CFR 46.101(b) Categories of Exempt Research**

- (b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:¹
- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
 - (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
 - (i) the human subjects are elected or appointed public officials or candidates for public office; or
 - (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
 - (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
 - (5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
 - (i) Public benefit or service programs;
 - (ii) procedures for obtaining benefits or services under those programs;
 - (iii) possible changes in or alternatives to those programs or procedures; or
 - (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

- (i) if wholesome foods without additives are consumed or
- (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

¹ Institutions with HHS-approved assurances on file will abide by provisions of Title [45 CFR part 46](#) subparts [A-D](#). Some of the other departments and agencies have incorporated all provisions of Title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at [45 CFR 46.101\(b\)](#) do not apply to research involving prisoners, [subpart C](#). The exemption at [45 CFR 46.101\(b\)\(2\)](#), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, [subpart D](#), except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Appendix B: **Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure¹**

Applicability

- (A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by [45 CFR 46.110](#) and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- (B) The categories in this list apply regardless of the age of subjects, except as noted.
- (C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- (D) The expedited review procedure may not be used for classified research involving human subjects.
- (E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
- (F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

- (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
- (b) from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner;

- (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction;
- (d) excreta and external secretions (including sweat);
- (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- (f) placenta removed at delivery;
- (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

- (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
- (b) weighing or testing sensory acuity;
- (c) magnetic resonance imaging;
- (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

- (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and [\(b\)\(3\)](#). This listing refers only to research that is not exempt.)
- (8) Continuing review of research previously approved by the convened IRB as follows:
- (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - (b) where no subjects have been enrolled and no additional risks have been identified; or
 - (c) where the remaining research activities are limited to data analysis.
- (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

¹ An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](#).

² Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR 46.402\(a\)](#).