What is Required to be Submitted to the IRB?

In accordance with the terms of the Federalwide Assurance (FWA) that Columbia University maintains with the federal Department of Health and Human Services, all *research* with *human subjects* must be submitted to the Institutional Review Board (IRB) for review, regardless of source of funding, or lack thereof.

Research is defined 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.

Human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains:
(1) data through intervention or interaction with the individual, or (2) identifiable private information.

Federal regulations permit exemption from IRB review for research with human subjects that involve only procedures in one or more of six specific categories (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.101). While review of such proposals by the *convened* IRB is not required, in accordance with the FWA the determination of eligibility for exemption must be made by the IRB. Therefore, all requests for exemption must be submitted via RASCAL for the appropriate determinations.

Proposals for all investigative activities that involve the use of humans or human specimens should be submitted to the IRB via RASCAL, even if the definitions of "research" and/or "human subject" may not appear to be met. In some cases, a determination of "not human subjects research" will be made; funding agencies and/or research sites may require documentation from the IRB of such a determination. A designation of "not human subjects research" does not imply that other institutional or agency approvals are not required, or that methods routinely employed in the ethical conduct of human subjects research should not be utilized.

The IRB encourages investigators, faculty, and staff to call the IRB office for consultation regarding whether or not an activity requires IRB review.

Tips To Facilitate Efficient Protocol Review Initial Submission

1. Complete all screens in RASCAL that are appropriate for a given study before submitting the protocol via RASCAL.

2. Attach all relevant material, e.g., funding proposal (grant or contract), sponsor protocol, investigator brochure (if the study involves an investigational drug), study instruments [i.e., questionnaire(s) or survey(s)], IND/IDE documentation, non-CU site approvals (e.g., permission to conduct the study).

3. Check "Cancer Center" in the Facilities section if the protocol is, in any way, cancer-related. This check-off routes the protocol to the Cancer Center's Protocol Review and Monitoring Committee (PRMC). The PRMC must review all cancer-related research even if it is NOT conducted at or by the Cancer Center.

4. Verify that information is consistent between documents, e.g., is the number of subjects listed on the data sheet the same as the number in the protocol and/or the consent form?

5. Name only one individual as Principal Investigator. This person must meet the criteria articulated in the Faculty Handbook to serve in this role.

6. Have all research personnel complete or update "Personal Information" in RASCAL. Use faculty titles, rather than clinical appointments.

7. Ensure that all personnel have completed required training (i.e., Human Subjects training for Columbia faculty/staff, HIPAA for all CUMC personnel). If non-CU research personnel are involved in the conduct of the research, attach a certificate of completion for equivalent training.

8. If requesting an exemption, thoroughly review the exemption categories to ensure that the protocol is eligible for exemption. Consult the IRB staff if necessary. If exemption is requested and the protocol is determined to be ineligible for exemption, it will have to be returned to the investigator to remove the exempt declaration.

9. Clearly identify the nature of the data collection, i.e., state whether it is anonymous, de-identified, coded, or non-coded. Explain what mechanisms are in place to protect private, identifiable information.

10. Describe in detail how subjects will be recruited (e.g., who will introduce the prospective subject to the study). Attach all advertisements, recruitment letters or other materials that will be used for the recruitment of subjects (e.g., videos, scripts for radio ads, etc.).

11. Construct and/or attach all applicable consent documents, (e.g., consent form(s), parental permission form, assent, information sheet), or provide a justification if requesting a waiver of consent in accordance with 45 CFR 46.116(d).

12. Include details of appropriate additional protections if subjects may be considered a vulnerable population, e.g., how capacity to consent will be determined, what procedures will be implemented to avoid coercion or undue influence factors.

13. Answer all questions on the Protocol-Specific Conflict of Interest form before electronically "signing" the form.

14. Attach a cover letter if the protocol includes any factors that may not be self-evident (e.g., eligibility for review per the terms of a cooperative amendment, collaborative relationships, unique funding arrangements, issues that may arise during the review that have been resolved by a specific CU IRB during the review of a similar protocol, etc.).

Resubmission (in response to Correspondence)

1. Respond via correspondence; be sure to address ***all*** questions and concerns.

2. Revise the protocol, consent forms, or other documents as necessary.

3. Reattach all consent forms built in RASCAL that were detached for editing.

(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.

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure[1]

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 children[2], 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;

Columbia University IRB
Subpart D – Research with Children
Reviewer Checklist Template

SUBPART D DETERMINATIONS – Select the appropriate category for this research project of the four (404, 405, 406, 407) described below. The criteria immediately following each choice must be satisfied in order for that determination to be made. Include your rationale for selecting the category in respective text field.

"408" refers to 45 CFR 46.408 and 21 CFR 50.55: Requirements for permission by parents or guardians and for assent by children.

404 **45 CFR 46.404 and 21 CFR 50.51**

a. Research not involving greater than minimal risk.

408 Request for waiver of parental permission/assent in accordance with 45 CFR 46.116(d)?
☐ Yes ☐ No

Parental Permission ☐ One Parent (adequate per regulations, unless waiver eligible) ☐ Both Parents

405 **45 CFR 46.405 and 21 CFR 50.52**

Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child involved in the study. (Both a. and b. below must be satisfied.)

a. the risk is justified by the anticipated benefit to the subjects.

b. the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

408 **Parental Permission** ☐ One Parent (adequate per regulations) ☐ Both Parents

406 **CFR 46.406 and 21 CFR 50.53**

The research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
(Items a., b., and c. below must be satisfied.)

a. The risk related to the research represents a minor increase over minimal risk.

b. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations presented by available alternative approaches.

c. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.

408 **Parental Permission** ☐ Both Parents (required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child).

407 **45 CFR 46.407 and 21 CFR 50.54**
(DHHS Secretarial consultation required prior to approval if study is federally funded; if not federally funded, IRB will form a subcommittee to make the required determinations.)
Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health/welfare of children.

a. the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

408 **Parental Permission** ☐ Both Parents (required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child)

ASSENT REQUIREMENTS

408 **Assent Requirements:**
Are age appropriate assent form(s), if appropriate, and adequate plans to obtain the assent of the child included?
☐ Yes ☐ *No ☐ N/A (not capable of providing assent)

*If no, has assent been waived according to 45 CFR 46.116(d) OR does the intervention or procedure involved in the research hold out a prospect of direct benefit that is important to the health or well-being of the children and available only in the context of the research
☐ Yes ☐ No (If no, assent plan must be obtained.)

Columbia University
Institutional Review Board
IRB Review Criteria
Primary Reviewer Form Template

	Please select one option for each question. RESPONSES TO ITEMS 1 THROUGH 5 (PLUS 6, 7, AND 8 WHEN APPROPRIATE) MUST BE "YES" IN ORDER TO APPROVE A PROTOCOL (per 45 CFR 46.111 and 21 CFR 56.111)	YES	NO	NA	NEI (Not Enough Info)
1	Are risks to subjects minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and whenever appropriate, by using procedures already being performed?	☐	☐		☐
2	Are risks to subjects reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result?	☐	☐		☐
3	Is the selection of subjects equitable considering the purposes of the research and the setting in which the research will be conducted?	☐	☐		☐
4	a. Will informed consent be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116 OR	☐	☐	☐	☐
	b. May some or all of the elements of consent be appropriately waived?	☐	☐	☐	☐
5	a. Will informed consent be appropriately documented, in accordance with, and to the extent required by §46.117 OR	☐	☐	☐	☐
	b. May written documentation of consent be appropriately waived?	☐	☐	☐	☐
6	When appropriate, does the research plan make adequate provisions for monitoring the data collected to ensure the safety of subjects?	☐	☐	☐	☐
7	When appropriate, are there adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data?	☐	☐	☐	☐
8	If subjects are likely to include vulnerable populations, are there additional safeguards in place to protect the rights and welfare of these subjects?	☐	☐		
9	Do you concur with the administrative pre review comments?	☐	☐*		
10	*Please provide details for any pre review comments with which you do not agree: Additional comments:				
11	Once approved by the IRB, recommended approval period:	☐ 6 months ☐ 12 months ☐ other:			

HUMAN SUBJECT RESEARCH DHHS 45 CFR 46 DECISION CHART