CU IRB — Institutional Review Board

Human Subjects Review Committee

Columbia University in the City of New York

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Columbia University Human Research Protection Program

Columbia University IRB

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Related Links
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News & Announcements

Visit the Morningside IRB Office on Wednesday's
from 1:00-3:00 without an appointment*

When: Any Wednesday
Where: Studebaker Building
615 West 131st Street, 3rd Floor
(Building entrance is on W. 132nd Street due to construction)
Time: 1:00 pm – 3:00 pm

*Alternatively an appointment may be scheduled
by calling 212-851-7040.

Current list of CUMC IT certified systems:

https://secure.cumc.columbia.edu/cumcit/secure/security/scp_systems.html

6/26/2013	Fall 2013 IRB Meeting Schedule Released
6/18/2013	**How to submit a Modification and/or Renewal for your Protocol to the CU IRB-Morningside** Date: Friday, August 23, 2013 Time: 3:30-4:30 Location: Hamilton 603 RSVP: https://calendar.columbia.edu/sundial/webapi/register.php?eventID=65941
6/18/2013	**New Faculty Training: Human Subjects Research Protections & How to Submit a Protocol to the CU IRB- Morningside** Date: Wednesday, August 21, 2013

The IRB is required to make the following determinations when reviewing a study (45 CFR 46.111 - Criteria for Review). These are based on the ethical principles set forth in the Belmont Report.

- Risks to subjects are minimized. (*Beneficence*)
- Risks to subjects are reasonable in relation to anticipated benefits. (*Beneficence*)
- Selection of subjects is equitable. (*Justice*)
- Informed consent will be sought from each prospective subject. (*Respect for Persons*)
- Informed consent will be appropriately documented. (*Respect for Persons*)
- When appropriate, the research plan makes adequate provisions for monitoring the data. (*Beneficence*) (*Respect for Persons*)
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. (*Beneficence*) (*Respect for Persons*)
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, the mentally disabled, or economically disadvantaged or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. (*Justice*) (*Beneficence*) (*Respect for Persons*)

EXEMPT RESEARCH

Federal regulations for the protection of human subjects in research (DHHS 45 CFR 46) require prospective IRB review and approval of activities that involve both "research" and "human subjects" as defined in the regulations, as well as monitoring and other oversight responsibilities.

However, the regulations include a provision (45 CFR 46.101(b)) whereby research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from the requirements of the regulations.

The exemption categories do not apply to all research with human subjects. Please see questions and answers which follow the table below.

Category **1** 45 CRF 46.101(b)(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.
Category **2** 45 CRF 46.101(b)(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. Note: Except for observation of public behavior, this category does not apply to research that involves children.
Category **3** 45 CRF 46.101(b)(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.
Category **4** 45 CRF 46.101(b)(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.

Category **5** 45 CRF 46.101(b)(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.
Category **6** 45 CRF 46.101(b)(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.

Question: Are the exemptions different for research involving children?

Answer: One of the six exemptions of research involving human subjects is narrowed in scope by Subpart D's additional protections for research involving children. The other five exemptions apply to research involving children as human subjects in the same way that they apply to research involving adults.

The narrowed exemption is the exemption at 45 CFR 46.101(b)(2), which generally applies to research involving educational tests, interviews or survey procedures or observation of public behavior, if the data are recorded without individual identifiers, or if disclosure of the recorded responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation. Where children will be involved as research subjects, however, the use of survey or interview procedures is eliminated from this exemption, and so is research involving the observation of public behavior if the investigators participate in the activity being observed.

In other words, the only research activities involving children that may fall under this exemption are those involving observation of public behavior where the investigators do not participate in the activity being observed. To be exempt, these activities must also meet the condition that the data are recorded without individual identifiers, or the condition that disclosure of the recorded responses would not place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation. Otherwise, all the requirements of the human subjects regulations apply.

Question: Are the exemptions different for research involving prisoners?

Answer: The exemptions are not applicable to research that involves prisoners.

EXPEDITED REVIEW

The federal regulations for the protection of human subjects in research (DHHS 45 CFR 46.110 and FDA 21 CFR 56.110) provide a mechanism by which one member of the IRB may act for the Board in the review of new protocols, renewals, and modifications that meet specific criteria. This process is referred to as expedited review.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers must ensure that all review criteria are met, and may exercise all of the authorities of the IRB except that the reviewers **may not disapprove** the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

Initial & Continuing Review

The categories of research that may be reviewed by an expedited review process at the time of initial and/or continuing review (as specified below) were agreed upon by both DHHS and FDA and subsequently published in the Federal Register on November 9, 1998 (63 FR 60364-60367).

As authorized by 45 CFR 46.110 and 21 CFR 56.110, the expedited review provision applies to 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 categories listed below.

Notification of protocols (new and renewal) and modifications approved via an expedited review procedure is provided to IRB members via the full Board meeting minutes.

Initial and Continuing Review categories:

Category **1** 63 FR 60364/7(1)	Clinical studies of drugs and medical devices when only when (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.
Category **2** 63 FR 60364/7(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, 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.

Category **3** 63 FR 60364/7(3)	Prospective collection of specimens by noninvasive means.
Category **4** 63 FR 60364/7(4)	Collection of data by 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.)
Category **5** 63 FR 60364/7(5)	Data, documents, records, specimens that have been collected, or that will be collected 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.)
Category **6** 63 FR 60364/7(6)	Data from voice, video, digital, or image recordings made for research
Category **7** 63 FR 60364/7(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.)

Continuing Review Categories:

Category **8** 63 FR 60364/7(8)	Continuing review of approved research previously approved by the convened IRB as follows:
8(a)	where the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
8(b)	where no subjects have been enrolled and no additional risks have been identified; or
8(c)	where the remaining research activities are limited to data analysis.
Category **9** 63 FR 60364/7(9)	Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2-8 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.

Modifications

45 CFR 46.110(b)(2)	Modifications: minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Levels of IRB Review Relative to Research Methodology

	"Not human subjects research"	**Exempt (from requirements of federal regulations)**	**Eligible for Expedited Review**	**Requires Full Board review**
Survey	Questions are designed such that no information ***about*** the respondent is obtained. Interaction between the researcher and the subject is occurring but the definition of human subject is not met because no information ***about*** a living individual is collected. It is irrelevant in this example whether identifiers are collected or not because the definition of human subject must be met before consideration is given to level of review, starting with the question of whether an exemption applies (for which the presence or absence of identifiers is important). Ex. School principals are contacted for data about enrollment, grade levels taught, absence policies.	Questions are designed to elicit information ***about*** the respondent or another living individual. Whomever the information is ***about*** is the human subject. The data collected must either be anonymous (i.e., no identifiers recorded), or, if they contain identifiers, not reasonably place the subjects at risk of harm if their responses were disclosed. Per the regulations, for this exemption to apply, all subjects must be adults. Ex. Face to face survey of adult college students involving questions about their experiences buying course books online. Identifiers could be collected as a breach of confidentiality would not place the subjects at risk of harm. Ex. Online survey of school principals seeking their opinion of their district's absence policies. Identifiers could be collected as a breach of confidentiality would not place the subjects at risk of harm.	Questions are designed to elicit information ***about*** the respondent or another living individual. Whomever the information is ***about*** is the human subject. The risk to subjects as a result of participation in the research must be determined to be no more than minimal. Informed consent must be obtained, and written documentation (signature of subject) provided, unless waiver criteria are met. Ex. Face to face survey of students involving questions about their adjustment to campus life as a freshman, including a self-assessment (verbal summary) of psychological status during that time. Identifiers are collected so that a follow-up survey may be conducted. Primary risk is breach of confidentiality; risk is minimal but harm could be suffered if responses indicated poor adjustment and were inadvertently released.	Questions are designed to elicit information ***about*** the respondent or another living individual. Whomever the information is ***about*** is the human subject. Risk to subjects as a result of participation may be more than minimal. Informed consent must be obtained, and written documentation (signature of subject) provided, unless waiver criteria are met. Ex. Face to face survey of students involving questions about their activities as a freshman living on campus, including questions about sexual activity, illegal substance abuse, and written self-assessment of psychological status during that time. Identifiers are collected so that a follow-up survey may be conducted. Primary risk is breach of confidentiality; risk is greater than minimal as illegal activities may have been disclosed.

	"Not human subjects research"	Exempt (from requirements of federal regulations)	Eligible for Expedited Review	Requires Full Board review
Analysis of Secondary data	Analysis of dataset that contains no direct (e.g., name, address, birthdate, Social Security number) or indirect (e.g., data that may be combined to readily identify the individual) identifiers. Ex. Analysis of publicly available U.S. census data. Ex. Analysis of dataset obtained from colleague where dataset contains no identifiers and no link to identifiers. Data are not such that individual identities could readily be ascertained through evaluation of a combination of available datapoints.	Analysis of existing data with the dataset to be analyzed procured under procedures where the researcher had access to identifiers (e.g., with permission of department) but did not record identifiers. Ex. Extraction from and analysis of data from a departmental or facility (e.g., school, medical center department, corporation) database with temporary access provided by the department/facility pursuant to an agreement between the researcher and department specifying the data that could be extracted and articulating that no identifiers could be recorded.	Analysis of existing data, including direct or indirect identifiers, wherein the risk of harm to subjects (the individuals to whom the data apply) as a result of the analysis is considered to be no greater than minimal. In the majority of situations, the principal risk is breach of confidentiality. Informed consent must be obtained or the requirement for informed consent waived by the IRB. Ex. Extraction from and analysis of non-sensitive data from a departmental or facility database with identifiers included so that the data may be correlated with data from other sources. Ex. Analysis of dataset received from legitimate holder of the data (e.g., school, medical center department, corporation, researcher who collected the data), where data include identifiers but risk to subjects presented by analysis of the data is minimal.	Analysis of existing data, including direct or indirect identifiers, wherein the risk of harm to subjects (the individuals to whom the data apply) as a result of the analysis is considered to be greater than minimal. In the majority of situations, the principal risk is breach of confidentiality. Informed consent must be obtained. Ex. Analysis of dataset received from legitimate holder of the data (e.g., school, medical center department, corporation, researcher who collected the data), where data include identifiers and risk to subjects created by analysis of the data may be greater than minimal (e.g., subjects are HIV-infected, survivors of childhood abuse, or prisoners and private information related to these factors are included). Informed consent for the secondary analysis must be obtained.

***Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.**

Human subject means 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.

***Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.**

RASCAL Study Description Help Text
August 22, 2009

Provide a detailed description of your proposed study here. You may copy and paste from a word processor file; if you use this method, please select "View Study Description" before submission, to evaluate the pasted text for conversion errors, and correct any that are found. Please structure this description using headings 1 through 11 below. If an element is not applicable, include the heading, followed by "Not applicable".

ABBREVIATED REQUIREMENTS: If this is a **multicenter, industry sponsored trial, or a study that is sponsored by a national cooperative group** (e.g., ACTG, NCI Cooperative Oncology Group), this field may be limited to items #7, 8, 9, and 10, provided that all other items are addressed, in detail, in the sponsor's protocol and related documents.

1. Study Purpose and Rationale .
Include pertinent background description with references that are related to the need to do this study. If this is a clinical trial, the background should include both preclinical and clinical data. Be brief and to the point.

2. Study Design and Statistical Procedures .
Provide sufficient details so that the adequacy of the statistical procedures can be evaluated including power calculations based on the number of participants to be entered into the study.

3. Study Procedures
Describe the procedures in sufficient detail so that a reviewer who is not familiar with them can comprehend what is to be done and can evaluate any risks. Delineate procedures that are already being performed for diagnostic or treatment purposes from those that are being done for research, i.e., clearly identify those procedures that would be occurring whether or not the individual was participating in this research.

4. Study Drugs or Devices
If this is a drug, device, or biologic study, describe how the drug or device works and past experience. [Be sure to complete the Investigational Products section for each applicable article.]

5. Study Instruments (e.g., Questionnaires, Interview Outlines, Focus Group Guides)
Describe any study instruments that will be used, and identify which are standardized instruments. Attach a copy of each in RASCAL

6. Study Subjects .
Give detailed inclusion and exclusion criteria and number of patients to be enrolled based on the statistical description and any other considerations. This information

should relate to the background information provided above, and must be consistent with information entered in the Subjects section. If this is a clinical trial, this should include a description of the disease and the goals of therapy.

7. Recruitment
Describe in detail how participants will be recruited including type (e.g., newspaper advertisements, posters) and location (e.g., CUMC or NYPH, private practices, clinics). Attach a copy of each written advertisement, and the script for each recruitment media or method that is verbal (e.g., video, telephone script).
If this is a CUMC study, remember that it is a CUMC policy that researchers generally cannot directly approach a patient for recruitment until that patient has been informed of the study by their physician who has ascertained and documented that the patient is willing to discuss the study with the investigators.

8. Informed Consent Process
Describe how consent will be obtained, including by whom (i.e., list one or more titles, roles, or names), when, and by what method (e.g., use of consent form requiring signature, verbally in-person, verbally by telephone). Be sure to describe means of communicating if non-English speaking, illiterate, or other vulnerable persons will be included among study subjects. Also if necessary, describe any visual aids or devices that may be used to help explain a complicated procedure or process.

9. Confidentiality of Study Data
Describe how this will be maintained (if it is to be maintained) locally, and during transmission to another site, if applicable. Include a clear description of how data will be stored, specifically indicating whether data will contain direct or indirect identifiers. Describe protections related to accessing the study data, whether in an electronic or paper form.
Please note that "deidentified" means that identifiers have been removed and no one (research team or others) can identify from whom the data or sample was collected. "Coded" means that the data/specimens are labeled with a code number, and there is a link between the respondent/donor and the data/specimen, i.e., someone can identify from whom the data/sample was collected if they have the link to the code. For any coded data/samples, indicate who, if anyone on the research team has access to the identifiable data.

10. Privacy Protections
Describe how subject privacy will be protected, and the limits to protection. Privacy protection may be summarized as safeguarding an individual's expectation that the information they offer will be held in confidence. Protections should cover (e.g.,) screening activities, HIPAA provisions, forums such as focus groups where private information may be shared, and recordings of research activities, as applicable. Limitations such as compelled disclosure and mandatory reporting should also be described.

11. Potential Risks
Describe risks including data on risks that have been encountered in past studies. That is, if the occurrence of a certain adverse event was 20%, include those data in this description.

12. Data and Safety Monitoring
Describe how data and safety will be monitored locally to identify unanticipated problems (i.e., events, outcomes, or occurrences that are unexpected, at least possibly related to the research, and suggest an increase in risk of harm to subjects or others).

13. Potential Benefits
This description should also be based on accrued data from related studies that have been completed. There should be a rational description of why such benefits are expected based on current knowledge. If there is unlikely to be direct benefit, describe benefits to society.

14. Alternatives
If this is a clinical trial involving therapy, describe alternative therapies providing data to support their efficacy or lack of efficacy. An important alternative is also not to participate in this research.

15. Research at External Sites
If CU investigators will be conducting research at one or more non-CU site(s), additional information is required. This includes, but is not limited to, plans for authorization and/or IRB approval at each site, explanation of funding and organizational relationships, description of procedures at each site, and plans for data and safety monitoring. Details, as applicable to the various types of situations that may occur, are provided in the CU IRB Standard Operating Procedures, Section V, which are available on the Policies and Guidance pages of the IRB websites.

16. Columbia as Lead Institution
If CU will serve as the lead institution for a multicenter study, specific information about management of information related to safety of subjects must be provided. This includes, but is not limited to: 1) obtaining and maintaining IRB approval at each site; 2) ensuring that each site follows consent procedures and utilizes consent documents approved by the designated IRB (if the designated IRB is not the CU IRB, then the IRB-approved consent document must be similar to the CU IRB-approved consent document with regards the content and style of the document); and 3) plans for data and safety monitoring. Additional information is provided in the CU IRB Standard Operating Procedures, section 5, on the Policies and Guidance pages of the IRB websites.

COLUMBIA UNIVERSITY
INFORMED CONSENT DOCUMENT

[Title of Study]

[Rascal Protocol Number]

Investigator: , Department

Telephone:

Investigators' statement

We are asking you to be in a research study [Sponsored by]. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be in the study. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When all your questions have been answered, you can decide if you want to be in the study or not. This process is called 'informed consent.'

PURPOSE

[State that this is a research activity. Describe the purpose of the activity.]

BENEFITS

[Describe the expected benefits to individual subjects and/or society. If there are no personal benefits, so state.]

PROCEDURES

[Describe the procedures involved. Include the commitment of time for each, the total amount of time involved, and how long the study will last. As appropriate, specify size of samples to be taken and names and doses of substances to be given. Describe questionnaires and interviews and describe or provide examples of the most personal and sensitive questions. State that subjects may refuse to answer any question or item in any test, inventory, questionnaire, or interview. Include the use of medical, academic, or other records, photographs, audio or visual recordings.]

RISKS, STRESS, OR DISCOMFORT

[Include information on the risks, including side effects, stress, discomforts, or the invasion of privacy which might result from each procedure.]

OTHER INFORMATION

[State whether data will be confidential (linked to identifiers) or anonymous (no links). If data will be linked to identifiers, please state who will have access to identifiable data. Describe how the data will be used and how long they will be retained. State that subjects may refuse to participate or may withdraw from the study at any time without penalty or loss of benefits to which they are otherwise entitled. Include a description of inducements (money, service, course credit) subjects may receive for participation.]

PARTICIPATION

Participation in research is entirely voluntary. You may refuse to participate or withdraw from participation at any time without jeopardizing your employment, student status or any other entitlements. The investigator may withdraw you at his/her professional discretion.

ALTERNATIVES TO PARTICIPATION

Generally there are no alternatives to participation in social and behavioral sciences research other than choosing not to participate, as most of the research is non-therapeutic in nature. If, however, the study involves an experimental treatment or therapy or program for which there are standard therapies, treatments or programs, these should be noted here with contact information so that participants are aware of these options. If no alternatives other than non participation are available to participants, this should be stated here.

PRIVATE INFORMATION

Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed without your separate consent, except as specifically required by law.

CONTACT INFORMATION

If at any time you have questions regarding the research or your participation, you should contact the investigator, name, who will answer all questions. His/Her telephone number is (xxx) xxx-xxxx. You should also contact the investigator or a member of the research staff if you have any concerns or complaints about the research.

If at any time you have comments regarding the conduct of this research or questions about your rights as a research participant, you should contact the Institutional Review Board (IRB) Administrator at (212) 851-7040.

PARTICIPANT'S STATEMENT

I have read the above purpose of the study, and understand my role in participating in the research. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later, about the research, I can ask the investigator listed above. I understand that I may refuse to participate or withdraw from participation at any time without jeopardizing my employment, student status or other rights to which I am entitled. The investigator may withdraw me at his/her professional discretion. If I have questions about my rights as a research participant, I can call the Institutional Review Board office at (212) 851-7040. I certify that I am 18 years of age or older and freely give my consent to participate in this study. I will receive a copy of this document for my records.

Subject's signature/consent: _____ Date: _____

Name: _____

INVESTIGATOR'S STATEMENT

I have discussed the proposed research with this participant, and in my opinion, the participant understands the benefits, risks and alternatives (including non-participation) and is capable of freely consenting to participate in the research.

Signature _____ Date: _____
Member of the Research Team

Print Name: _____

Sample Children's Assent Form

We are doing a study to try to learn about people who tell the truth and people who lie. We are asking you to help because we don't know very much about whether kids your age expect people to lie or tell the truth. If you agree to be in our study, we are going to ask you some questions about people. We will want to know if you think they usually tell the truth or if they usually lie. For example, you will be asked if a politician, teacher, parent, or other people usually lie or tell the truth.

You can ask questions at any time that you might have about this study. Also, if you decide at any time not to finish, you may stop whenever you want. Remember that these questions are only about what you think. There are no right or wrong answers because this is not a test.

Signing this paper means that you have read this or had it read to you and that you want to be in the study. If you don't want to be in the study, don't sign the paper. Remember, being in the study is up to you, and no one will be mad if you don't sign this paper or even if you change your mind later.

Signature of Participant _____ Date _____

Signature of Investigator _____ Date _____

Consent Requirements for Waivers

Waiver of Consent - based on the following criteria

Waiver of consent acceptable (all of the following elements apply)

- The research involves no more than minimal risk to the subjects;
- The waiver will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver; and
- Whenever appropriate, the subjects will be provided with additional information after participation

OR

Waiver of consent acceptable (all of the following elements apply)

- 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: (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; and
- The research could not practicably be carried out without the waiver or alteration.

Waiver of Written Documentation of Consent - based on the following criteria

Waiver of written documentation of consent acceptable (all of the following elements apply)

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

OR

Waiver of written documentation of consent acceptable (all of the following elements apply)

- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

"Helpful Hints" for IRB Review
45 CFR 46.111 (Criteria for Review)

RISKS TO SUBJECTS ARE MINIMIZED (*Beneficence*)
Points to consider:

1. Identify the potential/possible risks
2. Determine the level of risk
3. What is the probability and magnitude of the risks?
3. How are these risks minimized? Are these procedures adequate? For example, if there is a chance that someone could become upset either during or after an interview session, is there a qualified person present to assist the subject and/or should the researcher provide referrals in case someone becomes upset after they leave the research session.

RISKS TO SUBJECTS ARE REASONABLE IN RELATION TO ANTICIPATED BENEFITS (*Beneficence*)
Points to consider:

1. Identify the risks
2. Identify any benefits (to the individual subject and to society or group)
3. Weigh the risk/benefit ratio

SELECTION OF SUBJECTS IS EQUITABLE (*Justice*)
Points to consider:

1. Who is the targeted population?
2. Why is this population targeted?
3. Would this person or population potentially benefit from the research?
3. Is this population being targeted because of ***ease of access?***
If ease of access only, how innocuous is the research?
3. What are the inclusion/exclusion criteria? Are they appropriate?
4. What are the screening procedures?
4. Consider the recruitment process; Coercive? Deceptive?
5. Compensation – is compensation coercive? Would subjects participate only for the money?

INFORMED CONSENT WILL BE SOUGHT FROM EACH PROSPECTIVE SUBJECT (45 CFR 46.116 and 117) (*Respect for Persons*)

Points to consider:

1. Is there verbal or written consent?
2. Are subjects fully informed about the purpose of the research and what's expected for participation?
3. Is the consenting done in an appropriate timeframe?
4. Is the consent done in language understandable by the subject?
5. Does the consent form contain all the "elements of consent"?
5. Would a waiver or alteration of informed consent provide additional protection to subjects?

INFORMED CONSENT WILL BE APPROPRIATELY DOCUMENTED (45 CFR 46.116 and 117) (*Respect for Persons*)

Points to consider:

1. Is there a written consent form, parental permission form, assent form?
2. Are all the "elements of consent" in the document, in addition to the research specifics?
3. Is the document understandable to the population being enrolled?
4. Would a waiver of documentation (45 CFR 46.117) be appropriate to protect subjects?

WHEN APPROPRIATE, THE RESEARCH PLAN MAKES ADEQUATE PROVISION FOR MONITORING THE DATA

Points to consider:

1. Is this a greater than minimal risk study?
2. Is the investigator/IRB unsure of potential risks?
3. Would it be appropriate to require a "monitor" for the study?

WHEN APPROPRIATE, THERE ARE ADEQUATE PROVISIONS TO PROTECT THE PRIVACY OF SUBJECTS AND TO MAINTAIN THE CONFIDENTIALITY OF DATA

Points to consider:

1. Is data identifiable? If disclosed, could breach of confidentiality harm subjects?
2. Are the procedures in place adequate to protect the data; i.e., where stored, who has access, how long will the data be kept, IT protections?
3. In an interview – is the interview conducted in a safe, private location?
4. Would obtaining a "Certificate of Confidentiality" further protect the confidentiality of data; i.e. illegal behaviors, drug use, HIV status, etc.

WHEN SOME OR ALL OF THE SUBJECTS ARE LIKELY TO BE VULNERABLE TO COERCION OR UNDUE INFLUENCE, SUCH AS CHILDREN, PRISONERS, PREGNANT WOMEN, MENTALLY DISABLED, OR ECONOMICALLY OR EDUCATIONALLY DISADVANTAGED PERSONS, ADDITIONAL SAFEGUARDS HAVE BEEN INCLUDED IN THE STUDY TO PROTECT THE RIGHTS AND WELFARE OF THESE SUBJECTS.
Points to consider:

1. Additional protections for fully informed consent
2. Subparts B,C, and D apply for pregnant woman, prisoners and minors
3. Also consider other vulnerable individuals; elderly, cognitively impaired, employee/employer; teacher/student, educationally or economically disadvantaged, etc.
4. How are they recruited – what said?
5. What is the situation in which they are being recruited – is it coercive?
6. Does this particular population understand the research? If not, is there a representative to assist?
7. If the research includes multiple sessions, should the consenting of subjects be repeated at each session; i.e. those with diminished capacity to consent.

General Protocol Reviews

- Subject Selection: Inclusion/Exclusion Criteria (screening)
- Recruitment Process and documentation
- Consenting Process and documentation
- Data Collection methods and instruments
- Confidentiality Procedures for data storing and sharing of data
- Protection of privacy of subjects (if applicable)
- Data Maintenance/Destruction
- *The IRB needs to consider (have in their possession at the time of review) ALL documents that subjects will see and text of all verbal communications with subjects. (Are all documents attached to the protocol in RASCAL?)
- *Is the study description written in language that all IRB members can understand? Is the study description clearly contain all the information required to make the IRB determinations or is it just, for example, copied from a grant application?

Administrative considerations

University Policies such as Training and Education, Qualified PI status, HIPAA, Agreements, Proposal Tracking numbers, Hazardous Materials, Conflict of Interest

Special Areas:

International Research

1. Local context information; social, political, cultural as well as local laws and regulations
2. Local IRB review
3. Qualifications and experience of the researcher to conduct the research
4. Compensation – "culturally" not coercive
5. Translations – are translated documents required? Who will be translating the documents? Will a translator be required to conduct the research; i.e., interviews, etc.
6. Is data and/or samples transported back to the US – are the procedures adequate to protect the confidentiality of the data and privacy of subjects?

Review of Grants

1. Is the information in the grant consistent with the human subject's protocol?
2. What are the differences? (Personnel, title, dates, methods of data collection, hypothesis, consenting process, etc)
3. Is the entire grant (including face page and budget) attached to the protocol?

Examples of data collection methods:

Questionnaires, surveys

1. Do the questions in the survey/questionnaire relate to the topic of research?
2. Are subjects informed ahead of time about the types of questions to be asked, especially if sensitive in nature (illegal behaviors, health status, emotional issues)
3. Are protections in place to protect the confidentiality of subject's answers? (dissemination and collection procedures)
4. What are the risks to subjects with the particular questions asked?
5. Are subjects told they don't have to answer any question they don't want or that they can stop without penalty?

Focus Groups

1. Are all subjects given a reminder at the beginning of the session about maintaining confidentiality outside the group?
2. Are all subjects told that they don't have to answer any question or speak about any topic they don't want?
3. Are the topics of discussion submitted with the protocol?
4. Where are the focus groups held? (a private location)
5. If session is recorded, are subjects told?
6. What are the procedures if one person in the group does not want to be recorded?

Screening

1. What are the screening procedures? (in-person, internet, questionnaires?)
2. What are the screening questions?
3. Who will be conducting the screening?
4. Are there protections in place to protect this information?
5. Will the information obtained from the screening be identifiable? Will the information be sensitive and/or personal?
6. Will the screening data be kept even if the subject does not meet the inclusion criteria? If so, how will this data be maintained?
7. If identifiable, has the subject consented to the researcher maintaining this information? If so, does the consent include how long the data will be kept, who will have access, what the data will be used for, etc?

Interviews

1. Where are interviews held? (privacy)
2. Are subjects told ahead of time the types of questions
3. How are answers recorded?
4. Are subjects told in advance that the interview will be recorded?
5. Who is conducting the interviews? (is this an appropriate person?)

Secondary Analysis of Existing Data

1. Is the data identifiable – either directly or indirectly?
2. Is the data coded or de-identified
3. How sensitive is the data?
4. Are protections in place to protect the data once in researcher's possession?
5. Who has access to the data?
6. What will the data be used for?
7. Are any agreements between the owner of the data and the researcher?

Biological Samples (urine, blood, saliva, etc)

1. Have subjects consented to the use of the samples for research purposes?
2. Are the samples collected for research purposes only or are they taken from samples collected during standard of care?
3. Are the samples de-identified?
4. Are the samples being transferred to another organization/lab/institution for analysis?
    If so, will the data be shared with this other organization/lab/institution?
5. How are samples stored? How are they destroyed?
6. Have subjects consented for future use of the samples? If so, indicating "future use" is not acceptable – must say for what type of research, etc.
7. Who has access to samples and/or data?
8. Is approval for hazardous materials required?
9. Have STV forms been completed?

February 2, 2012

How to Manage Documents in Rascal

(Adapted from "User's Guide for RASCAL IRB Module" found on the CU IRB Web site - http://www.columbia.edu/cu/irb/ pp 77-79.)

Please note that these instructions only refer to attached documents in Rascal and not Rascal generated consent forms.

Documents can be "gotten rid of" in two ways: they can be **deleted** or they can be **archived.** However, you can only do one or the other, either delete or archive, not both. The one you can use depends upon the protocol's status.

- **Delete - Before you submit a new protocol/new modification/new renewal to the IRB, you can "delete" any document that you have attached to the protocol.** When you create a renewal or a modification, the RASCAL system copies all of the material from the previously-approved submission. This includes all of the attached documents. At this point, you can delete any of the attached documents. This does not delete these documents from RASCAL entirely, just from this new renewal or new modification. They still exist attached to the previous (approved) submission. Click on Attach Documents in the left hand column of the protocol to do this.

- **Archive - Any documents that were attached to a resubmitted protocol/modification/renewal (already submitted), but which has not yet been approved, can no longer be deleted, they can be only "archived."** This is done by clicking the box in the column on the right. When you re-submit your protocol (or modification or renewal), the document will be marked as inactive, but it will still be visible with the submission. Archived documents are not carried forward with a subsequent modification or renewal. Click on Attach Documents in the left hand column of the protocol to do this.

A renewal or modification should include only the current versions of any study documents.

Misusing or under-using the document management in Rascal results in confused and confusing submissions to the IRB. Better management of Rascal documents helps to facilitate the IRB review and reduce the need to clarify/return protocols.