

Human Subjects Research at Columbia

CU Morningside IRB

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<http://www.columbia.edu/cu/irb>

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Objectives

- Clarify “research” with “human subjects”
- Explain IRB function, scope
- Describe the IRB process and requirements
- Explain how to “submit” to the IRB
- Provide links to additional information

Does your study/project involve research with human subjects?

...such as interviewing, administering questionnaires or surveys, conducting focus groups, reviewing secondary data previously collected about people, or otherwise collecting data about people?

Then you need to submit a protocol for approval by the CU IRB.

Columbia University has a comprehensive Human Research Protection Program (HRPP).

No human subjects research (including recruitment, pilot studies, informal interviews, etc.) can begin until IRB review and approval has been obtained.

Research

“Research” is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)]

Human Subjects

“Human Subject” is defined as a living individual about whom an investigator (whether a professional or a student) conducting research obtains:

(1) data through intervention or interaction with the individual or (2) identifiable private information. [45 CFR 46.102(f)]

Surveys/Questionnaires/Interviews

- Are “not human subjects research” if:

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.

Check with the IRB

Analysis of Secondary Data

Is “not human subjects research” if:

it is an analysis of a 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.

Check with the IRB

IRB Mission

- The mission of the Institutional Review Board is to protect the rights and welfare of human research participants.
- The Morningside IRB at Columbia is a committee composed of CU faculty, a CU staff member, a CU graduate student, and an unaffiliated individual.

Does your project need to be submitted for IRB review?

1. Are you conducting research?
2. Are you conducting research that involves human subjects?

IF YES TO BOTH, IRB REVIEW IS REQUIRED.

Unsure? Check with the IRB

IRB Review

Research projects are reviewed at one of three levels, depending on the level of risk to the human subjects and other factors specified in the regulations.

The federal guidelines define the categories of review.

Level of Review

- **Exempt** - Exempt studies at Columbia must be submitted to the IRB for a determination that they are exempt from the regulations.
- **Expedited** - are reviewed by the Chair or his designee.
- **Full Board** -The protocol is reviewed at a convened meeting of the IRB at which a majority of members are present. Recommendation for action must be voted upon and a majority must approve the recommendation.

What Research Is Exempt ?

- Only studies that are low risk to subjects.
- Studies that fit into one of 6 exempt categories (See Exempt handout).

Exempt Determinations

At CU, the IRB Chair makes the exemption determination.

Exempt protocols need to be submitted in Rascal.

Exempt 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.

What Research is Eligible for Expedited Review?

- Involves no more than minimal risk
- Falls into 1 of 9 Expedited categories (See Expedited categories).
- Does not need review by the Full Board; reviewed by the Chair of his/her designee.

Definition of Minimal Risk

“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.

Expedited Review Category 7- Surveys and Interviews

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.

What Research Receives Full Board Review?

Protocols not eligible for
exemption or expedited review

Examples of Full Board Research

- Research asking questions that are sensitive (i.e., illegal behaviors) or likely to be stressful to the subject (i.e. child abuse, domestic violence) particularly if the risk is greater than minimal.
- Many (although not all) types of research involving children, pregnant women, fetuses, prisoners, and other vulnerable populations.

Full Board (cont.)

The protocol is reviewed at a convened meeting of the IRB at which a designated quorum of members are present. A recommendation for action must be voted upon, and a majority must approve the recommendation.

IRB Meetings Fall 2009

Full Board Review Schedule

Protocol Submission Deadline	IRB Convened Meeting Date
Thursday, December 23, 2010	Thursday, January 6, 2011
Thursday, January 6, 2011	Thursday, January 20, 2011
Thursday, January 20, 2011	Thursday, February 3, 2011
Thursday, February 3, 2011	Thursday, February 17, 2011
Thursday, February 17, 2011	Thursday, March 3, 2011
Thursday, March 3, 2011	Thursday, March 17, 2011
Thursday, March 17, 2011	Thursday, March 31, 2011
Thursday, March 31, 2011	Thursday, April 14, 2011
Thursday, April 14, 2011	Thursday, April 28, 2011
Thursday, April 28, 2011	Thursday, May 12, 2011
Thursday, May 12, 2011	Thursday, May 26, 2011
Thursday, May 26, 2011	Thursday, June 9, 2011

Informed Consent

- **All expedited and full board protocols require informed consent** (unless a waiver is approved). (See the “Wavier of consent” handout)
- See the IRB Web site link:

http://www.cumc.columbia.edu/dept/irb/policies/General_requirements_for_informed_consent.html

- Rascal contains a “Consent form Builder”
- The IRB recommends that for exempt studies, subjects be provided with the information normally provided in informed consent.

The IRB must determine if...

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent will be sought from each prospective subject (unless a waiver is approved)
- Informed consent will be appropriately documented (unless a waiver is approved)

More determinations...

- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain and monitor the confidentiality of data.
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of subjects.

Vulnerable Populations

- Children (will require parental permission and child assent)
- Pregnant women
- Prisoners (requires review by a prisoner advocate)
- Economically, educationally disadvantaged
- Elderly
- Cognitively impaired
- Mentally disabled

Submission Issues

The manner in which data are recorded and maintained influence the decisions of the IRB.

IRB Terminology Related to Data Collection **Anonymous vs. Confidential**

- **Anonymous** – the identity of the respondent cannot be determined by anyone at anytime; no links exist between the data and the individual about whom the data are recorded.
- **Confidential** (is not anonymous) - protection of study participants' data such that an individual participant's data is protected and will not be disclosed except to another authorized person.

IRB Terminology Related to Data Collection

- **De-identified** – identifiers have been removed from the dataset; links between the data and the individual exist but are not readily accessible to the researcher at CU;
- **Coded** – identifiers have been removed from the dataset but can readily be found through the use of a master list that is accessible to the investigator;
- **Identifiable** or non-coded – the identity of the subject is documented, linked or associated with the data.

How to Apply for IRB Approval at Columbia

Step One

The CU IRBs uses an electronic submission system called Rascal.

- Complete the required Human Subjects Protection Training: [TC0087 - Human Subjects Protection Training](#)
- This course is available through RASCAL at <https://www.rascal.columbia.edu>.

Who Takes This Test?

Principal Investigators, Co-Investigators, Research Staff, as well as anyone “engaged” in the research:

- has contact with subjects, such as obtaining consent and/or
- has access to identifiable data.

Step Two

- Go to the IRB web site to review the current guidance and policies. The web address is <http://www.columbia.edu/cu/irb>.
- Review all the policies that may apply to your research.

Step Three

- The next step is to create a protocol in RASCAL. This will be your IRB application.
- Go to the RASCAL home page and click on "Human Subjects" and then log in.
- Click on "Create a Protocol" to begin creating your IRB application.
- You may need to complete a Conflict of Interest statement in Rascal.

Principal Investigator

- Note that the Principal Investigator must be a full time member of the Faculty at specific ranks, or an Officer of Research as described in the Faculty Handbook. The Faculty Handbook can be found online at:
<http://www.columbia.edu/cu/vpaa/fhb/>.
- For student research, the Faculty Advisor should be listed as PI on the student's IRB application.
- Students may be co-investigators

Rascal will prompt you to enter
the specifics.

Purpose/Hypothesis

- Use layman's terms
- Concise and to the point –described the purpose/aims of the human subjects study.

Study Description

(see Study Description handout)

Study Purpose and Rationale

Include pertinent background description with references that are related to the need to do this study.

Study Design and Statistical Procedures

Provide sufficient details so that the adequacy of the statistical procedures can be evaluated based on the number of participants to be entered into the study.

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.

Study Description cont.

Potential Risks

Describe risks including data on risks that have been encountered in past studies.

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.

Study Description cont.

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.

Recruitment

Describe in detail how participants will be recruited including advertisements, online process, etc.

Confidentiality of Study Data

Describe how this will be maintained (if it is to be maintained).

What to Attach to your Submission:

- All recruitment materials (contact letters, e-mail texts, phone scripts, flyers)
- Grant proposals (attach the entire grant including the face page and budget)
- Dissertations
- Surveys
- Interview questions
- All consents

Observations

- Location
- What is recorded
- Is the information identifiable
- Is the observation recorded?
 - audio/video
 - Where maintained, for how long
 - Who has access
- Please review the IRB recommendations for *Audio/Video/Photographic Recording of Human Subjects* found at <http://www.columbia.edu/cu/irb/policies/index.html#irb>.

Secondary Data

Are you analyzing data obtained from another source?

Requires IRB review if it contains private identifiable information (either direct identifiers or indirect identifiers) because it meets the definition of “human subject.”

Provide documentation of permission to use the data from the source of the data (i.e. Data Use Agreement). Describe the data.

Records Review

- Explain what records are reviewed
 - Medical
 - School
 - Criminal
 - Public
- Publicly Available?
 - Provide link where found or provide documentation from the source
- Identifiable, de-identified, or coded
 - Are records recorded in an individually identifiable fashion?
 - Who has access to “master list”?

Focus Groups

- Describe what topic areas will be discussed
- Remind subjects about confidentiality
- Remind subjects that they do not have to answer any questions they do not want
- Recording: Audio or Video ?

Please review the IRB recommendations for
*Audio/Video/Photographic Recording of Human
Subjects* found at

<http://www.columbia.edu/cu/irb/policies/index.html#irb>.

- Include procedures if someone says no to recording

Collaborations

If your research will be conducted through collaboration with another organization or individual, you will need to document that organization's approval of your research.

If that organization has an IRB, you will also need to secure IRB approval from that organization.

International Research

Research should be sensitive to the cultural and political issues of the country in which the research is being conducted.

Minimally, documentation must be submitted by the investigator that the research has been assessed by someone knowledgeable and experienced about research and the local cultures/politics/norms.

International Research (cont.)

The research may need to be reviewed and approved by an ethics review committee (ERC) in the host country.

The International Compilation of Human Subject Research Protections is a listing of the laws, regulations, and guidelines that govern human subjects research in many countries around the world.

See <http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>

The New York Times

Reporters Tell of North Korea Arrest

By CHOE SANG-HUN

Published: *September 2, 2009*

“SEOUL, South Korea — Two American journalists freed by [North Korea](#) after four and half months of captivity have admitted that they did cross into North Korea.”

The New York Times

“Ms. Ling and Ms. Lee said they “took extreme caution” to protect their sources and the people they interviewed. During their detention, they said, they swallowed notes and damaged videotapes to destroy incriminating evidence. But they did not clarify what had happened to the videotapes...”

The New York Times

“The reporters acknowledged having visited a foster home in China for the children of North Korean women who had become refugees. Lee Chan-woo, the South Korean pastor who founded the foster home, said the Chinese police raided his home two days after the journalists were arrested and interrogated him based on videotapes the police had taken from the crew.”

“Mr. Lee said he was forced to close his five foster homes in China and was deported.”

International Research

See the *International Research and Local Review* handout.

- Local IRB approval may be required
- Local context information is required
- Translations
- Qualifications/experience of researcher
- Local permissions
- Local laws and regulations

Enrollment of Non-English Speaking Subjects in Research

Non-English Speaking Subjects are to be adequately provided with the information necessary to exercise informed consent.

For Columbia's Policy, see http://www.columbia.edu/cu/irb/policies/documents/Nonenglish_Speaking.doc.

HIPAA

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") extends significant new privacy rights to subjects concerning the use or disclosure of their medical information.

If private health information is collected (e.g. HIV status, diagnosis of disease, etc.) a HIPAA Authorization may be required.

Publicly Available Datasets

<http://www.columbia.edu/cu/irb/policies/documents/UseofPubliclyAvailableDatasets.FinalDRAFT.113007.pdf>le Datasets

Research projects involving only the analysis of de-identified datasets available from the following institutions do not qualify as “research” with “human subjects” and therefore, need not be submitted to the IRB for review or a determination of exemption.

1. Columbia University Electronic Data Service (EDS):
<http://www.columbia.edu/acis/eds/>.
2. Inter-University Consortium for Political and Social Research (ICPSR):
<http://www.icpsr.umich.edu/index.html>.
3. U.S. Bureau of the Census: < <http://www.census.gov/>>.
4. National Center for Health Statistics: < <http://www.cdc.gov/nchs/>> .
5. National Center for Education Statistics: < <http://nces.ed.gov/>>.
6. National Election Studies: < <http://www.electionstudies.org/>>.

Proof read your protocol before submitting, get approvals, submit

- Hit the “Print Menu” and print off a copy of the protocol to proof read before submitting
Are there inconsistencies in your protocol?
Have you attached all required documents including a consent form/script?
- “Notify Approvers” (PI) in Rascal
- After all approvers have “approved” the protocol in Rascal, hit “**SUBMIT**” or the IRB will never receive your protocol.

Helpful Hints: Review the IRB Web Site

<http://www.columbia.edu/cu/irb>

Review the [Frequently Asked Questions](#) link on the left of the home page.

Review the University and IRB policies that may apply to your research. See the [Policies and Guidance](#) link

If your submission is not complete the protocol will be “Returned” and this will delay your approval.

- The protocol will be returned and a correspondence will be sent through Rascal describing what needs to be done.
- Please review each item and correct your submission.
- You need to describe where the changes are made by sending back a “correspondence” in Rascal.
- If all the return items are not addressed, the protocol will be returned again.
- After correcting the missing items, you must “**SUBMIT**” again or the IRB will not be able to review and approve your protocol.

Common problems that delay approval requiring a “Return”

- Not having a PI according to CU policy
 - Study personnel who haven't completed the required training (addition training needed for research with minors and research collecting private health info)
 - Population Age listed is not accurate (Minors <18)
 - Not attaching all documents/verbal text that will be used with subjects (recruitment materials, flyers, consents, questionnaires, surveys, focus group questions, international research documentation, etc.)
 - Not providing enough information in the Study Description (e.g., how subjects will be recruited, how subjects will be consented, what confidentiality procedures will be used, info on risks, benefits, etc. See Study Description handout)
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More helpful IRB Web links

- [Frequently Asked Questions](#) link on the left of the home page.
- [Education & Training](#) link
- [How to Apply for IRB Approval](#) link
- [News & Announcements](#)
See the 2009 Meeting Schedule at:
<http://www.columbia.edu/cu/irb/documents/MSIRBmeetingschedule1.2009.doc>
- [Maintaining IRB Approval](#)
Modifying a Protocol
Renewing a Protocol (every year)
Terminating a Protocol

Rascal Help: 851-0213

Email: rascal@columbia.edu

<https://www.rascal.columbia.edu/>

Other CU research related links

- Office of the Executive Vice President for Research

<http://evpr.columbia.edu/>

- Sponsored Projects Administration

<http://spa.columbia.edu/>

- Research Compliance and Training

<http://www.columbia.edu/cu/compliance/>

MS IRB Open Office Hours

Every Wednesday 1:00 – 3:00 pm
615 West 131st Street, 3rd Floor

At the 3rd floor reception, ask for the IRB.

or

Call 212-851-7040 and make an
appointment with an IRB specialist

Contact CU IRB staff

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