

**Human Subjects Research  
and  
Institutional Review Board (IRB)**

**Guide to submitting IRB protocols on RASCAL**

## What is the Institutional Review Board (IRB) ?

The Institutional Review Board (IRB) is the Columbia University committee charged with protecting the rights and welfare of human subjects who participate in research. It also serves to protect the researchers and the University from potential harm when research projects that use people as subjects are conducted at Columbia.

IRBs were established at many Universities in the 1960's in response to federal research funding regulations have become even more common and comprehensive over the past 50 years.

## What Projects Should be Submitted to the Institutional Review Board (IRB)?

Human subject research is any research in which an investigator obtains information about a living individual:

- Through interventions or interaction with the individual  
or
- Through securing identifiable private information about the individual

Any project which meets either of the criteria above must be submitted for IRB review and approval prior to beginning the research.

Legal requirements to protect human subjects apply to a much broader range of research than many investigators realize. In addition to covering traditional biomedical studies, legal obligations to protect human subjects also apply, for example, to research that uses:

- Data collected through **intervention or interaction with individuals**. Intervention includes not only physical procedures (like drawing blood), but also manipulation of a subject's environment and some observations.
- **Private information** that can be used to identify individuals, even if the information was not collected specifically for the study in question. Examples include student records and medical records.
- **Bodily materials** such as cells, blood or urine, tissues, organs, hair, and nail clippings even if you did not collect these materials. (Such research may be considered exempt if materials are not personally identifiable and if the materials were collected *prior to the initiation of the research project*.)
- **Studies conducted to gain generalizable knowledge** about categories or classes of subjects such as employees, students, and/or patients. This includes a doctoral dissertation and a master's thesis.

## Types of IRB Review

- **Not human subjects:** Example: Analysis of existing anonymous (de-identified) data
- **Exempt:** A research project is exempt from IRB approval ***if it is determined by the IRB*** that the research is in a category exempted by federal regulations. These categories include research such as the following:
  - Research conducted in established or commonly accepted educational settings
  - Research involving the collection or study of existing data
  - Taste and food quality evaluation and consumer acceptance studies

See the flow chart at: <http://www.columbia.edu/cu/irb/policies/documents/-ExemptfromFBReview.pdf> to determine if your project is eligible to apply for exemption. Additional details of the exemption categories are listed in 45 CFR 46 Section 101(b)(1)-(6) and 21 CFR 56. 104(d) and on their web at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101>.

- **Expedited Review:** Review of proposed research by the IRB Chair or a designated voting member or group of voting members, rather than by the entire IRB Committee. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.
- **Full Board (Standard Review):** Review of proposed research at a convened meeting where a valid quorum of IRB members is present.

## IRB's criteria for review

- Risk to subjects is 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
- Informed consent will be appropriately documented
- When appropriate the research plans makes adequate provisions for monitoring the data
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data
- 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, economically disadvantaged or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

## Putting together an IRB protocol on RASCAL

Go to: <https://www.rascal.columbia.edu/> and log on using your UNI and password.

Click on "Create a protocol"

### 1. General information

You will see the screen below where you need to enter general information as shown:

Columbia University's RASCAL - Research Administration System - Mozilla Firefox

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**rascal** RASCAL Human Subjects

Logout | Help | Human Subjects | Animal Care | Proposal Tracking | Consent Forms | HIPAA Forms | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal

[IRB Menu]

- Tips for Efficient IRB review
- Tips for Consent Forms
- IRB's Reviewer Form
- Department of Pediatrics Pre-IRB Review Pediatric Human Subjects Checklist

Federal Regulations and Institutional Policies can be found at:  
<http://www.cumc.columbia.edu/dept/irb/policies/>

I believe this study qualifies as exempt

Originating Department Code  Department not defined

Sub department

Sub sub department

Submitting to

Previous Protocol Number

Affiliated Institutions   
American Museum of Natural History  
Barnard College  
Harlem Hospital

Protocol Begin Date

Protocol End Date

Title (maximum 500 characters)

Abbreviated Title (maximum 60 characters)

IRB of record (responsible for providing review and approval)

IRB number used by a non-CU IRB of record

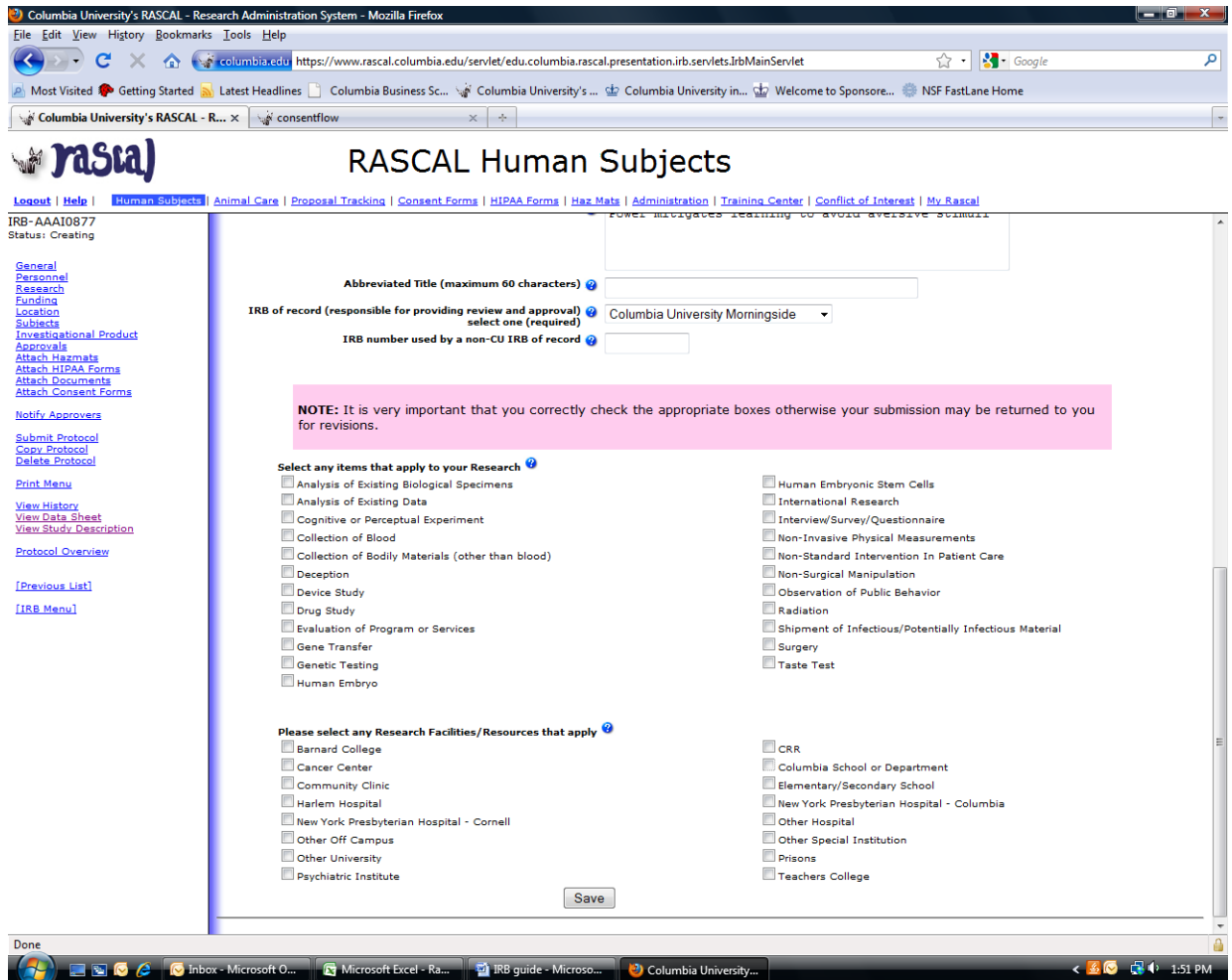
**NOTE:** It is very important that you correctly check the appropriate boxes otherwise your submission may be returned to you for revisions.

Select any items that apply to your Research  Analysis of Existing Biological Specimens  Human Embryonic Stem Cells

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You will also need to enter information about the study:



Once you complete this page you will see the following links on the left hand-side menu:

## 2. Personnel

- Add PI, and any key personnel
- Add Dimitra Koutsantoni as Administrator with 'Edit' permissions

## 3. Research

This is the most important part. It comprises the following sections:

- Research/protocol hypothesis
- Scientific abstract (max 250 words)
- Lay abstract (no word limit)
- Study description

The study description should be organized under the following headings:

1. Study purpose and rationale
2. Study design and procedures
  - Be as detailed as possible
  - include a timeline of the procedures as they will take place in the experiment

- If you will be using any equipment, detail how exactly you will use it and when, supply the product's name and manufacturer, state whether it is in good working order, and attach any safety guidelines and manufacturer's certifications.
  - Mention any potential risks and detail the steps that will be taken to mitigate those risks
3. Study subjects and recruitment
    - State how subjects will be recruited and include the recruitment text. If subjects will be compensated, state dollar amount of compensation
  4. Informed consent process
    - Detail the informed consent process (face to face, phone, electronic, verbal, written/when/by whom)
  5. Confidentiality of study data
    - Detail what steps will be taken to ensure confidentiality of data
    - Will participants be identifiable?
    - Where will data be kept?
    - Who will have access to the data?
    - How long will data be kept?
  6. Potential risks and benefits
    - Talk about any potential risks and detail the steps that will be taken to mitigate those risks. Think if any of the procedures has the potential to harm subjects in any (even miniscule) way and address this in your narrative.
    - Talk about the benefits of the study to social science and/or the society

#### 4. Funding

Add the sponsor (if any) of your research

#### 5. Location

Add location of your research (your office, Behavioral Lab, or any other location)

#### 6. Subjects

You will need to enter specific information about your research subjects as shown below:

- Gender
- Age
- Ethnicity
- Any special populations
- Recruitment media
- Subject population justification
- Compensation
- Compensation justification
- Consent form waiver/alteration request: Fill out this filed if there is any reason why the research cannot be feasibly be done without non-disclosure of full research procedures to participants.

- Recruitment URL

**RASCAL Human Subjects**

IRB-AAA10877  
Status: Creating

**General**  
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[Research](#)  
[Funding](#)  
[Location](#)  
[Subjects](#)  
[Investigational Product](#)  
[Approvals](#)  
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[Attach HIPAA Forms](#)  
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You are **Dimitra Koutsantoni (dk2617)** | Year **1** | Modification **00**

'Subject' refers to a human subject, defined as a living individual about whom an investigator obtains either data through intervention or interaction with that individual, or private identifiable information. Therefore, a record in a dataset or sample(s) from an individual may be considered a subject.

**Will the study collect Social Security Numbers?**  Yes  No

**Is there any intent to disclose Social Security Numbers outside of Columbia?**  Yes  No

**If Social Security Numbers will be collected, please provide a plan to protect confidentiality.**

**Is this a multi-center Study?**  Yes  No

**Target subject accrual at all sites:**

**Target subject accrual at this site:**

**Columbia University/New York Presbyterian Hospital Outpatient Subjects:**

**Columbia University/New York Presbyterian Hospital Inpatient Subjects:**

**Population Gender**

Males  %    Females  %    Non Specific  %

**Population Age**

0-7  %    8-17  %    18-65  %    >65  %    Non Specific  %

**Population Ethnicity**

African-American  %    Asian  %    Caucasian  %    Hispanic  %    Middle Eastern  %    Native American  %    Pacific Islander  %    Other  %    Non Specific  %

**Special Populations - check any that apply**

Frail elderly     Cognitively impaired  
 Educationally disadvantaged     Economically disadvantaged  
 Medically Compromised     No contact with subjects/data analysis only  
 Non-english speaking     Pregnant women/fetuses/in vitro fertilization

Done

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## 7. Human specimen

If your research involves collection of human specimen (such as saliva) you will need to complete this form:



Columbia University's RASCAL - Research Administration System - Mozilla Firefox

File Edit View History Bookmarks Tools Help

columbia.edu https://www.rascal.columbia.edu/servlet/edu.columbia.rascal.presentation.irb.servlets.IrbHumanSpecimenEntryServlet

### RASCAL Human Subjects - Add/Edit Human Specimen

Description (MAX 255 Characters) ?

Type ? ~Select Type~

Origin ? ~Select Origin~

Source of Specimen (MAX 255 Characters) ?

Method of Obtaining (MAX 255 Characters) ?

Length of Retention ?

How Sample and/or Specimen will be Labeled (MAX 255 Characters) ?

Specimens Will be Reused ?

Add

Done

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## 8. Approvals

Add departmental approvers: usually these include the PI, Co-PI and any key researchers

## 9. Attachments

- Consent forms
- Recruitment materials (fliers, videos, website)
- Research tools (surveys, questionnaires, tests, interview scripts, etc)
- Debriefing sheets (if any)
- Grant proposal and budget
- Equipment safety standards
- Related previously approved protocols

### Specific attachments

#### Consent form

- You can use the consent form builder on RASCAL

- Go to: <https://www.rascal.columbia.edu/> and log on using your UNI and password
- Click on “Create a consent form”

The form has the following fields:

- Research purpose
- Information on Research: detail the procedures in simple language
- Risks: explain any risks (even small) and detail what you will do to mitigate the risks
- Benefits: explain any direct benefits for participation. If there aren't any, state so but explain any general benefits (to social science, society etc)
- Confidentiality: details the steps you will take to protect participants confidentiality of data
- Compensation: detail the dollar amount compensation per hour (if any)
- Voluntary participation (standard text)
- Signatures (Minimally, a consent document that will be signed should have the following lines for signature and date: 1) Signature of the Subject or Participant; 2) Signature of the Person Obtaining Informed Consent; and 3) Investigator's signature)

Tips:

- Use one or two syllable words whenever possible
- Write short sentences and paragraphs
- Define all technical terms in lay language
- Organize information in sections with clear headings
- Use bullet points
- Address the consent document to the reader by using the active voice and the word "you" throughout, (i.e., "You are being asked to take part in a research study . . .").

Alternatively, you can complete and attach the sample consent form available on:

<http://www.columbia.edu/cu/irb/policies/index.html#irb> (Standard Format for Social/Behavioral Science Consent Documents)

### **Recruitment materials**

Any recruitment materials should contain the following information:

- The investigator should include the purpose of the experiments and/or briefly state what is expected of the subject.
- Should include the time commitment required of the subject.
- In summary form, the criteria that will be used to determine eligibility for the study
- A brief list of participation benefits, if any
- Should include the investigator's University department affiliation.
- Should state the location of the research, or advise participants to call for this information (note that certain changes in location may require IRB review if the change could affect subject confidentiality of possibly increase risks to subjects)
- Should list a contact name and phone number.
- Should not include the name of commercial sponsors or products.

- Should state a specific amount of money or simply state “Compensation Available.” Compensation should not be excessive to the nature of the project or be used as an inducement to participation

### **Debriefing sheet**

- Explain the purpose of the research
- Explain the procedures and the rationale behind procedures in simple lay language
- Supply contact information (PI’s and IRB’s)
- Use simple language: please see tips for consent form above

### **Final steps**

- Print and proofread the Data Sheet and the Study Description
- Check that you have attached all the relevant documents
- Notify approvers
- Submit the protocol

**For any questions please contact: Dimitra Koutsantoni, [dk2617@columbia.edu](mailto:dk2617@columbia.edu)**