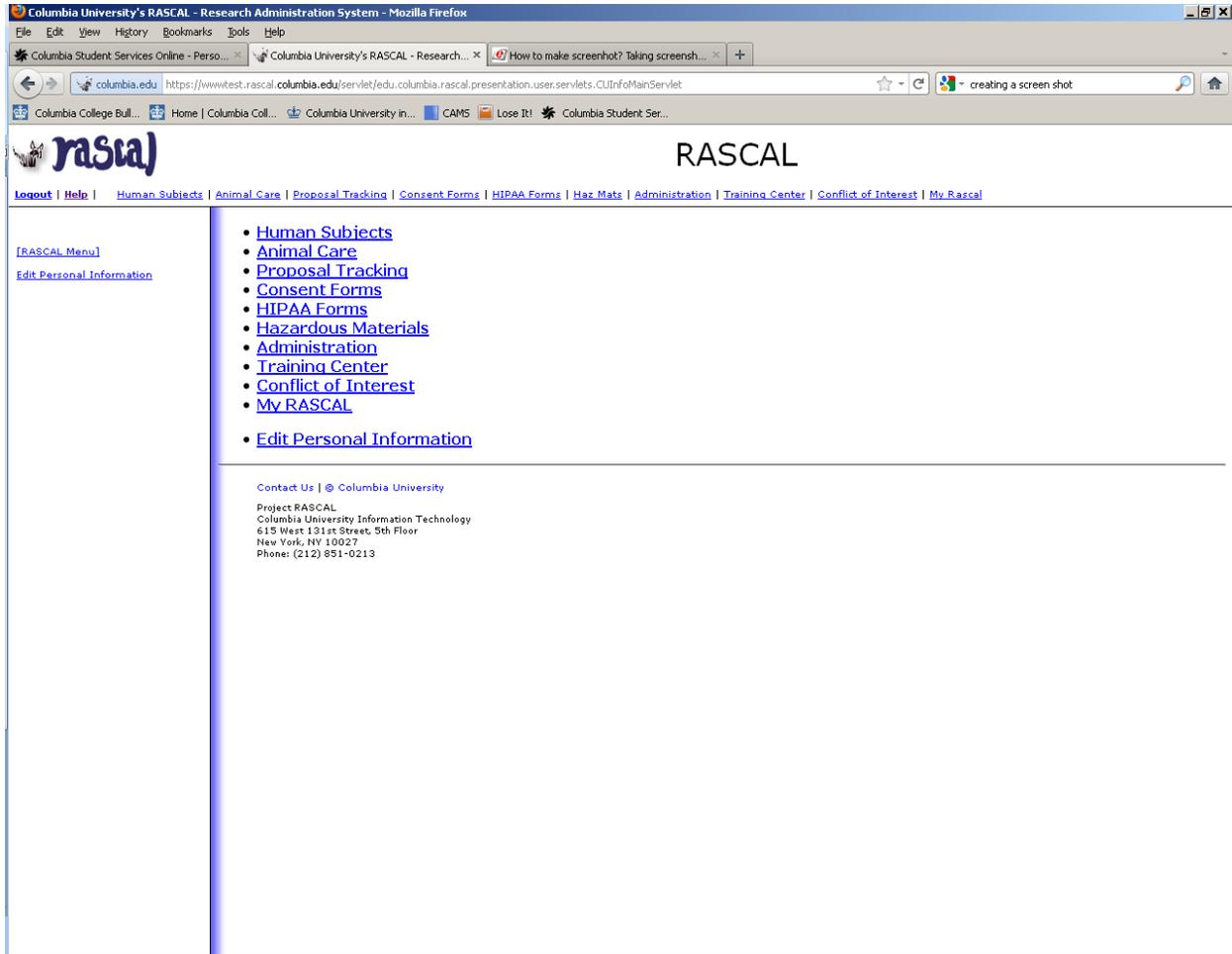


Guide to Creating a Protocol in RASCAL

1. Login to [RASCAL](#), and click on Human Subjects.



The screenshot shows the RASCAL web application interface. The browser title is "Columbia University's RASCAL - Research Administration System - Mozilla Firefox". The address bar shows the URL: <https://wwwtest.rascal.columbia.edu/servlet/edu.columbia.rascal.presentation.users.servlets.CUInfoMainServlet>. The page features the RASCAL logo on the left and the text "RASCAL" on the right. A navigation menu is located below the logo, containing links for Logout, Help, Human Subjects, Animal Care, Proposal Tracking, Consent Forms, HIPAA Forms, Haz Mats, Administration, Training Center, Conflict of Interest, and My Rascal. On the left side of the main content area, there are links for [RASCAL Menu] and Edit Personal Information. The main content area displays a list of menu items: Human Subjects, Animal Care, Proposal Tracking, Consent Forms, HIPAA Forms, Hazardous Materials, Administration, Training Center, Conflict of Interest, My RASCAL, and Edit Personal Information. At the bottom of the page, there is contact information for Project RASCAL at Columbia University, including the address (615 West 131st Street, 5th Floor, New York, NY 10027) and phone number (212) 851-0213.

Click on Create a Protocol and complete the following dialogue boxes, including the appropriate dates for your project.

The screenshot shows a web browser window titled "Columbia University's RASCAL - Research Administration System - Mozilla Firefox". The address bar shows the URL: <https://www.test.rascal.columbia.edu/servlet/edu.columbia.rascal.presentation.urb.servlets.IrbMainServlet>. The page header includes the RASCAL logo and the title "RASCAL Human Subjects". A navigation menu contains links for [Logout](#), [Help](#), [Human Subjects](#), [Animal Care](#), [Proposal Tracking](#), [Consent Forms](#), [HIPAA Forms](#), [Haz Mats](#), [Administration](#), [Training Center](#), [Conflict of Interest](#), and [My Rascal](#). The main content area features a list of links: [Create a Protocol](#), [Retrieve a Protocol: IRB-](#) followed by a text input field containing "XXXX9999" and a "SUBMIT" button, [Search for a Protocol](#), [Notification Queue](#), [Approve Protocols](#), [Rascal IRB Manual](#), [Helpful IRB Information](#), [Helpful HIPAA Information](#), and [Edit Personal Information](#). At the bottom, there is a "Contact Us" section for Project RASCAL, located at Columbia University Information Technology, 615 West 131st Street, 9th Floor, New York, NY 10027, with a phone number of (212) 851-0213.



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](#)

[\[IRB Menu\]](#)

GENERAL INSTRUCTIONS

For guidance and tools to facilitate protocol submission to the IRB, please visit our web site at: <http://www.cumc.columbia.edu/dept/irb/submit.html>

Tools include:

- 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

Protocol Begin Date

Protocol End Date

Title (maximum 500 characters)

Abbreviated Title (maximum 60 characters)

IRB of record (responsible for providing review and approval)
select one (required)

IRB number used by a non-CU IRB of record

Scroll down the same page to check all research items and facilities that apply to your project, and click save.

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

File Edit View History Bookmarks Tools Help

Columbia Student Services Online - Perso... Columbia University's RASCAL - Research... RASCAL | Office of Sponsored Projects Columbia University's RASCAL - Research...

columbia.edu https://wwwtest.rascal.columbia.edu/servelet/edu.columbia.rascal.presentation.urb.servelets.IrbMainServlet

Columbia College Bull... Home | Columbia Coll... Columbia University in... CAMS Lose It! Columbia Student Ser...

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]

Abbreviated Title (maximum 60 characters) [?] Project Title

IRB of record (responsible for providing review and approval) [?] select one (required) Columbia University Morningside

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 [?]

| | |
|--|---|
| <input type="checkbox"/> Analysis of Existing Biological Specimens | <input type="checkbox"/> Human Embryonic Stem Cells |
| <input type="checkbox"/> Analysis of Existing Data | <input type="checkbox"/> International Research |
| <input type="checkbox"/> Cognitive or Perceptual Experiment | <input checked="" type="checkbox"/> Interview/Survey/Questionnaire |
| <input type="checkbox"/> Collection of Blood | <input type="checkbox"/> Non-Invasive Physical Measurements |
| <input type="checkbox"/> Collection of Bodily Materials (other than blood) | <input type="checkbox"/> Non-Standard Intervention In Patient Care |
| <input type="checkbox"/> Deception | <input type="checkbox"/> Non-Surgical Manipulation |
| <input type="checkbox"/> Device Study | <input type="checkbox"/> Observation of Public Behavior |
| <input type="checkbox"/> Drug Study | <input type="checkbox"/> Radiation |
| <input type="checkbox"/> Evaluation of Program or Services | <input type="checkbox"/> Shipment of Infectious/Potentially Infectious Material |
| <input type="checkbox"/> Gene Transfer | <input type="checkbox"/> Surgery |
| <input type="checkbox"/> Genetic Testing | <input type="checkbox"/> Taste Test |
| <input type="checkbox"/> Human Embryo | |

Please select any Research Facilities/Resources that apply [?]

| | |
|---|---|
| <input type="checkbox"/> Barnard College | <input type="checkbox"/> CTSA-Clinical Research Resource(CRR) (former GCRC) |
| <input type="checkbox"/> Cancer Center | <input type="checkbox"/> Columbia School or Department |
| <input type="checkbox"/> Community Clinic | <input type="checkbox"/> Elementary/Secondary School |
| <input type="checkbox"/> Harlem Hospital | <input type="checkbox"/> New York Presbyterian Hospital - Columbia |
| <input type="checkbox"/> New York Presbyterian Hospital - Cornell | <input type="checkbox"/> Other Hospital |
| <input type="checkbox"/> Other Off Campus | <input type="checkbox"/> Other Special Institution |
| <input type="checkbox"/> Other University | <input type="checkbox"/> Prisons |
| <input type="checkbox"/> Psychiatric Institute | <input type="checkbox"/> Teachers College |

Save

After you save, the left menu will change to include additional pages for you to complete.

Click on Personnel and be taken to the following screen in which you can add your Principle Investigator (PI).

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

Protocol Number: IRB-AAAJ6203

| | | | |
|----------------------------|---------------------|------------|------------------------|
| Protocol Creation Date | 02/15/2012 at 11:31 | Department | COLUMBIA COLLEGE (410) |
| Principal Investigator | | Initiator | Hazel May (hm2135) |
| You are Hazel May (hm2135) | | Year | 1 Modification 00 |

GENERAL INSTRUCTIONS

For guidance and tools to facilitate protocol submission to the IRB, please visit our web site at:
<http://www.cumc.columbia.edu/dept/irb/submit.html>

Tools include:

- 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 410 COLUMBIA COLLEGE

Sub department []

Sub sub department []

Submitting to Morningside

Previous Protocol Number []

Affiliated Institutions [Manhattan Eye Ear and Throat Hospital
Valley Hospital
White Plains Hospital Center
-Standard Columbia Submission] -Standard Columbia Submission

Protocol Begin Date [] [] []

Protocol End Date [] [] []

Title (maximum 500 characters) The Title of Your Project

- Insert the UNI of your CU faculty adviser and click Add.
- The next screen will confirm whether or not your PI needs to complete the Conflict of Interest statement.
- Click on blue circle to add personnel; yourself as Co-Investigator.
- Follow the same process as for the PI: insert your UNI and select Co-Investigate for role. Click on Add to confirm.
- Click on Research to provide a Scientific Abstract and provide a Lay Abstract – a brief overview of what you want to study and how you plan to conduct the study

The screenshot shows a web browser window titled "Columbia University's RASCAL - Research Administration System - Mozilla Firefox". The address bar shows the URL: <https://wwwtest.rascal.columbia.edu/servlet/edu.columbia.rascal.presentation.irb.servlets.IrbPI>. The main content area displays the form "RASCAL Human Subjects - Add/Edit Principal Investigator".

The form includes the following fields and controls:

- Enter UNI (do not enter a name)**: A text input field.
- UNI Lookup**: A blue circular button with a right-pointing arrow.
- What is this person's role**: A dropdown menu currently set to "Principal Investigator".
- Edit/View**: A dropdown menu currently set to "Edit".
- Add**: A rectangular button at the bottom of the form.

A horizontal line is present below the form fields, and a small grid of dots is visible in the bottom right corner of the page.

Save each section and click on the blue circle next to Add Research/Protocol Hypothesis (just above the Scientific Abstract dialogue box).

The screenshot shows the RASCAL Human Subjects web application in a Mozilla Firefox browser. The browser's address bar shows the URL: <https://wwwtest.rascal.columbia.edu/servelet/edu.columbia.rascal.presentation.irb.servelets.IrbMainServlet>. The page title is "RASCAL Human Subjects".

At the top, there is a navigation menu with links: [Logout](#), [Help](#), [Human Subjects](#), [Animal Care](#), [Proposal Tracking](#), [Consent Forms](#), [HIPAA Forms](#), [Haz Mats](#), [Administration](#), [Training Center](#), [Conflict of Interest](#), and [My Rascal](#).

The main content area is titled "Research" and displays a table with the following information:

| Protocol Number | | IRB-AAA6203 | |
|----------------------------|-------------------------|-------------|------------------------|
| Protocol Creation Date | 02/15/2012 at 11:31 | Department | COLUMBIA COLLEGE (410) |
| Principal Investigator | Kathryn Yatrakis (kby1) | Initiator | Hazel May (hm2135) |
| You are Hazel May (hm2135) | | Year | 1 Modification 00 |

Below the table, a notice reads: "NOTICE: Do not open two Rascal browser windows at the same time. Do not work on this page if you are on a low-speed dial-up connection. Add Research/Protocol Hypothesis (REQUIRED)".

The interface contains three main text input areas:

- Scientific Abstract (MAX 250 words)**: Includes a "Spell Check Following Fields" button and a "Save" button. The text area contains the instruction: "Provide a brief overview of your research and your research plans. It conveys to a reader not schooled in your discipline what the research is about and how you plan to conduct the research."
- Lay Abstract**: Includes a "Save" button. The text area contains the instruction: "A lay abstract is a clear description of your ideas and plans. Be sure to answer the following questions: What methods will be used to answer the research question? What will the subjects be asked to do?"
- Study Description**: Includes a "Save" button. The text area is currently empty.

A left-hand sidebar contains various navigation links such as [General](#), [Personnel](#), [Research](#), [Funding](#), [Location](#), [Subjects](#), [Investigational Product](#), [Approvals](#), [Attach Hazmats](#), [Attach HIPAA Forms](#), [Attach Documents](#), [Attach Consent Forms](#), [Notify Approvers](#), [Submit Protocol](#), [Copy Protocol](#), [Delete Protocol](#), [Print Menu](#), [View History](#), [View Data Sheet](#), [View Study Description](#), [Protocol Overview](#), and [\[IRB Menu\]](#).

Write in your research questions, and click save.

The screenshot shows a web browser window titled "Columbia University's RASCAL - Research Administration System - Mozilla Firefox". The address bar shows the URL: <https://wwwtest.rascal.columbia.edu/servlet/edu.columbia.rascal.presentation.irb.servlets.IrbR>. The main content area is titled "Research/Protocol Hypothesis" and contains a large, empty text input field. Below the input field, there is a "Display Sequence" label with a question mark icon and a text box containing the number "1". To the right of the text box are two buttons: "Save" and "Spell Check".

Write in your research questions, and click save.

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

File Edit View History Bookmarks Tools Help

Columbia University's RASCAL - Research... Columbia College | Columbia College

columbia.edu https://wwwtest.rascal.columbia.edu/.../servlet/edu.columbia.rascal.presentation.irs.servlets.IrbMainServlet

hastings on hudson

Columbia College Bull... Home | Columbia Coll... Columbia University in... CAMS Lose It! Columbia Student Ser...

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-AAAJ6203
Status: Creating

Research

| Protocol Number | | IRB-AAAJ6203 | |
|------------------------|-------------------------|--------------|------------------------|
| Protocol Creation Date | 02/15/2012 at 11:31 | Department | COLUMBIA COLLEGE (410) |
| Principal Investigator | Kathryn Yatrakis (kby1) | Initiator | Hazel May (hm2135) |
| You are | Hazel May (hm2135) | Year | 1 Modification 00 |

NOTICE: Do not open two Rascal browser windows at the same time. Do not work on this page if you are on a low-speed dial-up connection.
Add Research/Protocol Hypothesis (REQUIRED) ?

| Research/Protocol Hypothesis | Edit | Delete |
|--|------|--------|
| First question is to explore second question is to find | ? | |

Scientific Abstract (MAX 250 words) Spell Check Following Fields

Provide a brief overview of your research and your research plans. It conveys to a reader not schooled in your discipline what the research is about and how you plan to conduct the research.

Save

Lay Abstract

A lay abstract is a clear description of your ideas and plans. Be sure to answer the following questions:
What methods will be used to answer the research question?
What will the subjects be asked to do?

Save

Study Description

Click on Attach Documents in order to upload your completed Undergraduate Study IRB Approval Request Form.

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

File Edit View History Bookmarks Tools Help

https://www.test.rascal.columbia.edu/servelet/edu.columbia.rascal.presentation.irb.servelets.IrbMainServlet

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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-AAJ6203
Status: Creating

[General](#)
[Personnel](#)
[Research](#)
[Funding](#)
[Location](#)
[Subjects](#)
[Investigational Product](#)
[Approvals](#)
[Attach Hazmats](#)
[Attach HIPAA Forms](#)
[Attach Documents](#)
[Attach Consent Forms](#)

[Notify Approvers](#)

[Submit Protocol](#)
[Copy Protocol](#)
[Delete Protocol](#)

[Print Menu](#)

[View History](#)
[View Data Sheet](#)
[View Study Description](#)

[Protocol Overview](#)

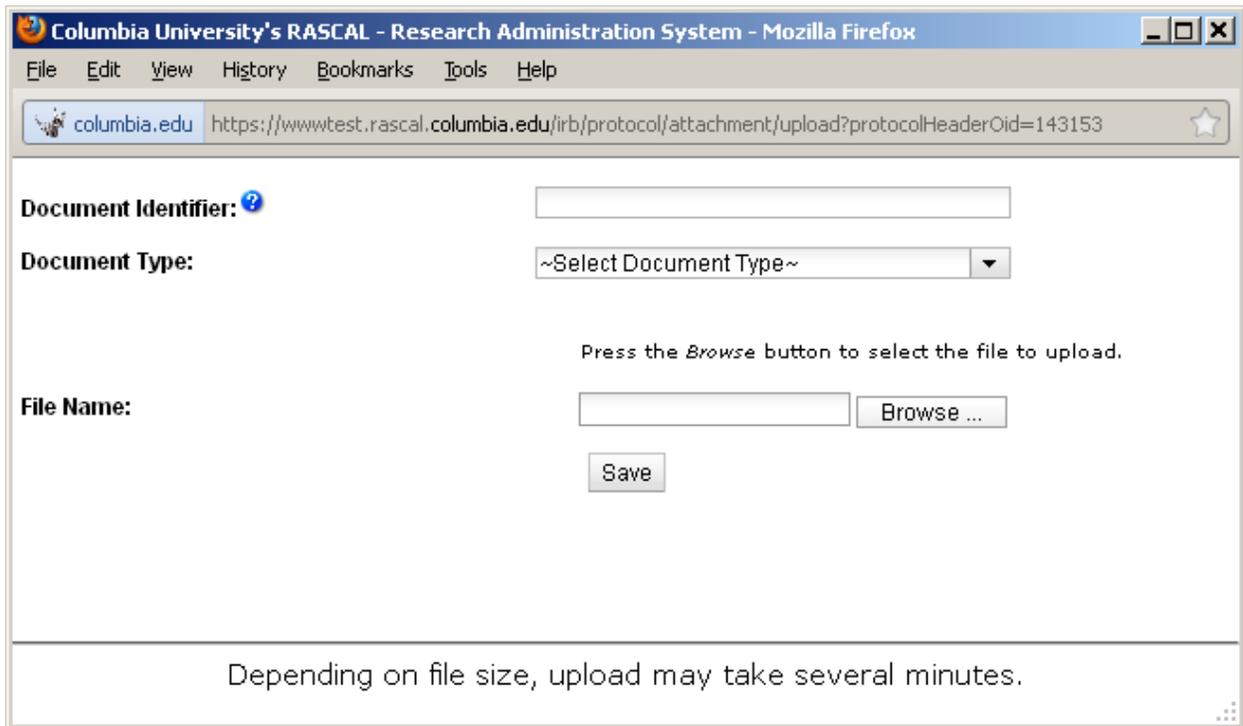
[\[IRB Menu\]](#)

Attach Documents

| | | | |
|------------------------|-------------------------|---------------------|------------------------|
| Protocol Number | | IRB-AAJ6203 | |
| Protocol Creation Date | 02/15/2012 at 11:31 | Department | COLUMBIA COLLEGE (410) |
| Principal Investigator | Kathryn Yatrakis (kby1) | Initiator | Hazel May (hm2135) |
| You are | Hazel May (hm2135) | Year 1 Modification | 00 |

Add Attachment  

- Identify this form as Other, and then save.
- Click on Funding, select No for the ARRA question, then click on the blue circle, select Unfunded, and save.
- Click on Location, click on the blue circle, and insert any relevant information such as city and country. Be as specific as you can be but note that you are not required to fill all fields



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

File Edit View History Bookmarks Tools Help

columbia.edu https://wwwtest.rascal.columbia.edu/irb/protocol/attachment/upload?protocolHeaderOid=143153

Document Identifier:

Document Type: ~Select Document Type~

Press the *Browse* button to select the file to upload.

File Name:

Depending on file size, upload may take several minutes.

Click on Subjects and complete all relevant sections and save.

The screenshot shows a web browser window titled "Columbia University's RASCAL - Research Administration System - Mozilla Firefox". The address bar displays "columbia.edu" and the URL "https://wwwtest.rascal.columbia.edu/servlet/edu.columbia.rascal.presentation.irb.servlets.IrbPr". The main content area features the heading "RASCAL Human Subjects - Add/Edit Location". Below the heading are four input fields labeled "Site", "Building", "Floor", and "Room". The "Site" field contains the placeholder text "Insert any relevant information". A "Save" button is positioned below the input fields. A horizontal line is drawn below the "Save" button. The browser's menu bar includes "File", "Edit", "View", "History", "Bookmarks", "Tools", and "Help".

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

File Edit View History Bookmarks Tools Help

columbia.edu https://wwwtest.rascal.columbia.edu/servlet/edu.columbia.rascal.presentation.irb.servlets.IrbPr

RASCAL Human Subjects - Add/Edit Location

Site

Building

Floor

Room

- Click on Attach Documents to add any relevant recruitment materials – such as a flyer, email copy, etc.
- Click on Attached Consent Forms to add the consent form that your subjects will be required to complete.
- Click Attach Documents to include all study instruments – surveys, interview guides, focus group discussion guides, psychological measures, etc. – and local context information if your research will be conducted in another country.
- Click Submit Protocol and click OK.

RASCAL Human Subjects

Attach Consent/Assent Form

| Protocol Number | | IRB-AAAJ6203 | |
|------------------------|-------------------------|--------------|------------------------|
| Protocol Creation Date | 02/15/2012 at 11:31 | Department | COLUMBIA COLLEGE (410) |
| Principal Investigator | Kathryn Yatrakis (kby1) | Initiator | Hazel May (hm2135) |
| You are | Hazel May (hm2135) | Year | 1 Modification 00 |

Attach Consent/Assent Form ⓘ

General
[Personnel](#)
[Research](#)
[Funding](#)
[Location](#)
[Subjects](#)
[Investigational Product](#)
[Approvals](#)
[Attach Hazmat](#)
[Attach HIPAA Forms](#)
[Attach Documents](#)
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[View Study Description](#)
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[\[IRB Menu\]](#)