



RASCAL Human Subjects

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Protocol Actions

Originating Department	OAD College and Arts & Scis (W/030UX)	Protocol Initiator	Rafael Santos (rs3275)
Protocol Year	1 Modification 00	Date Created	08/30/2017 10:17:38
Principal Investigator	Rafael Santos (rs3275)	You are	Rafael Santos (rs3275)

General Information

General Instructions

- Enter information in each section and be sure to SAVE your work
- This symbol means help information
- This symbol means lookup/add information
- *Dotted underline* means that hovering the cursor over the text will show a definition
- *Red asterisks indicate required questions
- No data on a page is saved until you receive the **green save confirmation** message. Please remember to save often!
- Following successful 'Save' of a page, review left hand menu for additional Pages to be completed
- While each individual page may be considered "complete" upon save, at the time of submission the system may identify additional areas where the information is inconsistent or incomplete between pages.

Please contact the Human Research Protection Office if you have questions about submitting to the IRB, or whether this study requires review.

CUMC Campus: (212) 305-5883 irboffice@columbia.edu <http://www.cumc.columbia.edu/dept/irb>
CU-MS and LDEO Campus: (212) 851-7040 askirb@columbia.edu <http://www.columbia.edu/cu/irb>

*Originating Department Code Please enter at least 3 characters

*From what Columbia campus does this research originate? 21 / 500

*Title (maximum 500 characters)

Protocol Version #

*Abbreviated Title (maximum 60 characters)

*Was this protocol previously assigned a number by an IRB?
 Yes No

*Is the purpose of this submission to obtain a "Not Human Subjects Research" determination?
 Yes No

Save

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7746 Highlight All Match Case 1 of 1 match

This Rascal protocol template should be utilized when conducting a study that ONLY involves a retrospective chart review of CUIMC-NYP patient records in which in-person interaction with subjects is not anticipated.

**Tips:

- Please select "Save" after each page.
- Selected the blue question mark icon for guidance on what is needed in each field.
- The links on the left-hand side are all pages that need to be completed prior to resubmission.
- The link of the left-hand side that is highlighted dark blue is the page that is currently accessed.

IRB-AAAR5752
Status: Creating

Abbreviated title	aa	Protocol Number	AAAR5752
Originating Department	OAD College and Arts & Scis (070350X)	Protocol Initiator	Rafael Santos (rs3275)
Protocol Year	1 Modification 00	Date Created	08/30/2017 10:17:38
Principal Investigator	Rafael Santos (rs3275)	You are	Rafael Santos (rs3275)

Attributes

*Special review type: Check all that apply or check "None of the Above" box.

Review for 45 CFR 46.118 Determination (involvement of human subjects is anticipated but is not yet defined)

Funding review for Administrative IRB approval (such as for Center or Training Grants)

None of the above

*IRB of record information: Will a Columbia IRB be the IRB that is responsible for providing review, approval, and oversight for this study?

Yes No I don't know

*Select the most appropriate response:

Columbia will be the IRB of record for the study procedures conducted by Columbia researchers (Note: this response will apply to most submissions).

Columbia has been formally designated as the *Central IRB* for all sites in this multicenter study.

Columbia will be the IRB of record for the study procedures conducted by Columbia researchers AND researchers from one or more other institution(s).
Note: Formal arrangements for Columbia to serve as a *Central IRB* are more appropriately captured in the previous option.

Columbia will be the IRB of record for the study procedures conducted by Columbia researchers and one or more investigators who are not affiliated with an institution. You will need to complete a request for an [Individual Investigator Agreement](#).

Is this research part of a multicenter study?

Yes No

*Please indicate if any of the following University resources are utilized:

Cancer Center Clinical Protocol Data Management Compliance Core (CPDM)

CTSA-Irving Institute Clinical Research Resource (CRR)

CTSA-Irving Institute Columbia Community Partnership for Health (CCPH)

None of the above

Save

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Please contact the Human Research Protection Office if you have questions about submitting to the IRB, or whether this study requires review.
CUMC Campus:
(212) 305-5833 | irboffice@columbia.edu
CU-MS and LDEO Campus:
(212) 851-7040 | askirb@columbia.edu

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- 1) “[x] None of the above” should be selected
- 2) “[x] Yes” should be selected if the CU IRB will be providing approval for the analysis conducted by CU researchers.
- 3) As this Rascal protocol template should be utilized when conducting a study that **ONLY** involves a retrospective chart review of CUIMC-NYP patient records, the response to this field should be **‘No.’**
- 4) “[x] None of the above” should be selected unless utilizing any of the listed university resources.



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Background

Abbreviated Submission:

The IRB has an abbreviated submission process for multicenter studies supported by industry or NIH cooperative groups (e.g., ACTG, HVTN, NCI oncology group studies, etc.), and other studies that have a complete stand-alone protocol. The process requires completion of all Rascal fields that provide information regarding local implementation of the study. However, entering study information into all of the relevant Rascal fields is not required, as the Columbia IRBs will rely on the attached stand-alone (e.g., sponsor's) protocol for review of the overall objectives.

If you select the Abbreviated Submission checkbox and a section is not covered by the attached stand-alone protocol, you will need to go back and provide this information in your submission.

Study Purpose and Rationale:

Provide pertinent background information with references that are related to the need to conduct this study. If this is a clinical trial, the background should include both preclinical and clinical data. Be brief and to the point.

Abbreviated Submission - This information is included in an attached stand-alone protocol.

Chart Review Protocol Template

Study Design:

Describe the methodology that will be used in this study, covering such factors as retrospective vs. prospective data collection, interventional vs. non-interventional, randomized vs. non-randomized, observational, experimental, ethnography, etc.

Abbreviated Submission - This information is included in an attached stand-alone protocol.

Statistical Procedures:

Provide sufficient details so that the adequacy of the statistical procedures can be evaluated including power calculations to justify the number of participants to be enrolled into the study. Definitions of subject terms such as enrolled and accrued as used for Rascal submissions can be found in the Subjects section.

Abbreviated Submission - This information is included in an attached stand-alone protocol.

- 1) Complete the text field to address the instructions found beneath each header
- 2) Alternatively, you may select the "[x] Abbreviated Submission" designation if a standalone protocol providing this information will be attached

IRB-AAAR5752
Status: Creating

Principal Investigator: Rafael Santos (rs3275) You are: Rafael Santos (rs3275)

Exempt and Expedited

The purpose of this page is to help researchers and the IRB assess whether exemption or expedited review is applicable. Submission of a complete protocol to the IRB is required in order for the IRB to make the necessary determinations. Please note a protocol cannot be approved as both exempt and expedited.

*Is the purpose of this submission to obtain an **exemption determination**, in accordance with 45CFR46.101(b)?
 Yes No

*Is the purpose of this submission to seek **expedited review**, as per the federal categories referenced in 45CFR46.110?
 Yes No

*Is the risk of harm to which subjects will be exposed as a result of this research no more than **minimal**?
 Yes No. The risk of harm will be greater than minimal.

*Select the category or categories of research into which study procedures fall.

Category 1: Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 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.

PLEASE NOTE: If blood is collected through an existing catheter, you do not qualify for expedited review under this category.

Category 3: Prospective collection of biological specimens for research purposes by noninvasive means. Examples include: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncanalulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples include: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). PLEASE NOTE: If extra tissue is being taken during a routine clinical procedure (i.e. additional tissue that is not being taken for diagnostic purposes), you do not qualify for expedited review under this category.

Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

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- 1) Studies that involve abstraction of identifiable data from patient medical records are generally not eligible for exemption. This would also be the case if any linkage between the abstracted data and the medical record exists.
- 2) Studies that involve analysis of existing data from the patient medical records are generally eligible for Expedited review, category 5.

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Originating Department	OAD College and Arts & Scis (070350X)	Protocol Initiator	Rafael Santos (rs3275)
Protocol Year	1 Modification 00	Date Created	08/30/2017 10:17:38
Principal Investigator	Rafael Santos (rs3275)	You are	Rafael Santos (rs3275)

Funding

*Is there any external funding or support for this project? Note: Funding that is applied for, or is being received as a gift, should be considered external support.
 Yes No

*Add Funding

Award Type	Funding Source Name	Name of awarding agency	Status	Award # or Application Date	Federal/State /Local Government Direct or Subcontract	What is the award covering?	Rascal PT Number	Modify	Delete
No data to display									

Save

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Please contact the Human Research Pro
 CU-MS Campus
 (212) 305-5883 | irboffice@columbia.ed
 CU-MS and LDEO Campus:
 (212) 851-7040 | asirb@columbia.edu

*Award Type: ~Select~

*Funding Source Name:

*What is the award covering: Entire Protocol Part of Protocol Only Providing Drug or Device

Rascal Proposal Tracking (PT) #:

Click here to choose from Finalized Rascal Proposals that you are listed on

Save

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1) Describe any funding on this page.

**Tip:

- A full funding application (face page, budget, and narrative) should be attached for all federal funding sources.
- Subcontract sites should be noted, their FWA provided, and a summary of their role described.

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Principal Investigator	Rafael Santos (rs3275)	You are	Rafael Santos (rs3275)

Locations
Add individual entries for each location where study procedures will take place under the purview of Columbia researchers. At least one location must be entered.

*Add Location

Location Type	Facility Name	Domestic or International	Geographic Location	Local IRB Ethics Approval	Local Site Approval	Modify	Delete
No data to display							

***Location Type:**
 Columbia/CUMC
 NewYork-Presbyterian Hospital @ Columbia
 Offsite

***Provide the building and facility name where the research is taking place:**

Save

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- 1) Add the location from which the data will be abstracted and the location at which your analysis will take place.

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Principal Investigator	Rafael Santos (rs3275)	You are	Rafael Santos (rs3275)

Personnel

*Add Personnel

Please be aware you must have a single Principal Investigator associated with your protocol.

UNI	Name	Role	Department	Edit/View	Obtaining Informed Consent	Modify	Delete
rs3275	Santos, Rafael	Principal Investigator	091200X - RES Institutional Review Board	Edit	Y		

Roles And Experience: s

Training and COI

The PI must ensure that each individual that is added as personnel has met the training requirements for this study (<http://www.cumc.columbia.edu/dept/irb/education/index.html>)
For help identifying which research compliance trainings are required for each personnel member, please visit the [Research Compliance Training Finder](#).

Name (UNI)	COI	HIPAA	HSP (CITI)	Research with Minors (CITI)	FDA-Regulated Research (CITI)	S-I	CRC	Good Clinical Practice (GCP)	GCP - Third-party tracking	Genetic Research Consent
	07/12/2018	03/14/2012	12/20/2017		01/15/2015					

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 CUMC Campus:
 (212) 305-5883 | irboffice@columbia.edu
 CU-MS and LDEO Campus:
 (212) 851-7040 | asire@columbia.edu

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- 1) Add CU personnel that will be involved in the abstraction of patient data or analysis. Principal Investigators must be full-time faculty members (Professor, Associate Professor, Assistant Professor, Instructor) or full-time Officers of Research (Senior Research Scientist/Scholar, Research Scientist/Scholar).
- 2) Ensure that all required training has been completed. All personnel must complete the HSP TC0087 course and CUIMC researchers must also complete the HIPAA TC0019 course in order to participate in research. The elective, Research with Minors training, found within HSP TC0087 is also required if you will analyze data from children/minors. For additional guidance, visit the Training Center section of Rascal.
- 3) Obtaining Informed Consent column should indicate, "N" for all personnel as no interaction with subjects will take place.

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Departmental Approvers

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Principal Investigator	Rafael Santos (rs3275)	You are	Rafael Santos (rs3275)

Departmental Approvers

Add Departmental Approvers

Approver	Position	Department	Delete
No data to display			

Department and Personnel Approvers have not been notified.

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 CUMC Campus: (212) 305-5883 | irboffice@columbia.edu
 CU-MS and LDEO Campus: (212) 851-7040 | askirb@columbia.edu

1) Add all approvers that may be required per your department.

**Tip: Studies originating from a Pediatrics department must list Fiona Sanders (fs2107) as an approver.



RASCAL Human Subjects

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Privacy & Data Security

*Indicate the methods by which data/research records will be maintained or stored (select all that apply):

Hardcopy (i.e., paper)

*Describe where and how the data will be stored:

Description of HARDCOPY storage

Electronic

*Where will the data be stored?

On a System

On an Endpoint

*Identify what type of endpoint will be used (select all that apply):

Desktop Computer

Laptop Computer

Mobile Device

Other

*Does this study involve the receipt or collection of Sensitive Data?

Yes No

If any Sensitive Data is lost or stolen as part of your research protocol, you must inform both the IRB and the appropriate IT Security Office (CUMC IT Security if at CUMC, CUIT if at any other University campus).

*What type of Sensitive Data will be obtained or collected? Select all that apply:

Personally Identifiable Information (PII), including Social Security Numbers (SSN)

*Will Social Security Numbers (SSNs) be collected for any purpose?

Yes No

Protected Health Information (PHI), including a Limited Data Set (LDS)

If any PHI is lost or stolen, you must inform both the IRB and the Office of HIPAA Compliance.

*Indicate plans for secure storage of electronic sensitive data: check all that apply

Sensitive data will not be stored in electronic format

Sensitive data will be stored on a multi-user system

*Provide a comma separated list of System ID numbers for the certified environment in which the Sensitive Data will be stored

0592

Sensitive data will be stored on an encrypted endpoint

By Selecting an Endpoint Device and approving this protocol for submission to the IRB, the PI is attesting that the device and any removable media that may be used have been or will be registered and/or will be maintained in compliance with the University's Information Security Charter and all related policies. It is important that this information is updated, during the course of the study, as new devices are added.

*Provide a description of how the confidentiality of study data will be ensured, addressing concerns or protections that specifically relate to the data storage elements identified above (e.g. hard copy, electronic, system, and/or endpoint):

Describe how data 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. Limitations such as compelled disclosure and mandatory reporting should also be described. 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 individual and his/her data, i.e., someone can identify from whom the data was collected if they have the link to the code. For any coded data, indicate who, if anyone, on the research team has access to the identifiable data.

- 1) Please ensure that the storage selections for all electronic data are consistent with the storage requirements for electronic Sensitive Data. Any necessary explanations should be noted in the text field found on this page (e.g., nonsensitive electronic data stored on both endpoint and system, sensitive electronic data only stored on encrypted endpoint).
- 2) Studies that involve abstraction of data from patient medical records involve sensitive data in the form of PHI.
- 3) Sensitive data stored electronically must be either stored on an encrypted endpoint device or on a CUIMC IT certified multi-user system. For a list of certified multi-user systems please select the following link: https://rsam.cumc.columbia.edu/RSAM_DEFAULT.aspx
**Please note that RSAM can only be accessed while on Columbia network or VPN.
- 4) Describe how data will be stored (ensure consistency with the above selections). Explain if data will be stored with direct identifiers or linked to identifiers via a code. If the latter, confirm that the key will be stored separately and explain how this key will be stored. Explain if and how data will be transferred externally and if this transfer will consist of a limited data set. If data will be used, analyzed or stored in multiple systems, all should be listed and described.

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***Is this project a clinical trial?**
 Yes No

***Is this project associated with, or an extension of, an existing Rascal protocol?**
 Yes No

Do study procedures involve any of the following?

***Analysis of existing data and/or prospective record review** Yes No

***Audio and/or video recording of research subjects** Yes No

***Behavioral Intervention?** Yes No

***Biological specimens (collection or use of)** Yes No

***Cancer-related research** Yes No

***Drugs or Biologics** Yes No

***Future use of data and/or specimens** Yes No

***Genetic research** Yes No

***Human embryos or human embryonic stem cells** Yes No

***Imaging procedures or radiation** Yes No

***Medical Devices** Yes No

***Surgical procedures that would not otherwise be conducted or are beyond standard of care** Yes No

Will any of the following qualitative research methods be used?

***Survey/interview/questionnaire** Yes No

***Systematic observation of public or group behavior** Yes No

***Program evaluation** Yes No

Will any of the following tests or evaluations be used?

***Cognitive testing** Yes No

***Educational testing** Yes No

***Non-invasive physical measurements** Yes No

- 1) Select "Yes" to the Analysis of Existing Data and/or Prospective Record Review" field.
- 2) Select "Yes" to the Future Use of Data and/or Specimens field if you anticipate utilizing the data in future research or if you will transfer the data to an external site and the recipient may utilize the data in future research. All data transfers require an appropriate data use/transfer agreement.

IRB-AAAF8402

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*Indicate whether the data that will be collected or utilized for the proposed study are in existence as of the current IRB submission date.

All of the data are in existence
 Some of the data are in existence and some will be generated in the future.
 None of the data currently exist.

*Provide the date range of the existing data, documents, or records (e.g., medical charts, school records, census data)

*Beginning Date:
*End Date:

Note that end dates beyond the initial IRB Protocol submission date or future requests for a date parameter extension beyond the provided end date may require informed consent and HIPAA Authorization to be obtained from subjects.

*Data will be obtained from (select all that apply):
 Columbia and/or NYP (e.g., departmental databases/systems, patient charts, Eclpsys, WebCIS, administrative/billing records, etc.)

*Select all that apply:
 Data to be analyzed were or will be collected for clinical care

*Provide the specific patient eligibility criteria and information that will be extracted by the study team or requested in a TRAC report, i.e., each data variable.
Provide the specific patient eligibility criteria AND each variable that will be extracted by the study team OR requested in a TRAC report

Data to be analyzed were or will be collected for nonresearch purposes other than for clinical care (e.g., student records, class evaluation, administrative records, etc.)
 Data originate from an IRB approved protocol
 Other

Outside Columbia and/or NYP:

*Will a member of the research team be abstracting data directly from source documents ?
 Yes No

If there is a data abstraction document/spreadsheet, attach it to the submission to complete study records. Though the IRB does not approve these documents, for reference purposes they are extremely helpful in understanding the scope of the proposed data collection.

*Select the applicable responses:
 The data, documents, or records to be reviewed/abstracted are those to which a member of the research team has legitimate access for non-research purposes (e.g., departmental patient database, physicians' patient clinical records, student records).
 Special authorization is necessary to review the records as the research team does not have access to the data, and a request will be or has been made to access the data.

Show de

- 1) The data are only considered retrospective if “[] All of the data are in existence” at the time of the protocol submission.
- 2) Include the beginning date and end date of the data to be analyzed. Note that the end date should not surpass the date of the protocol submission in order for the study to be considered retrospective. Note that if a modification is submitted to include dates beyond the initial IRB Protocol submission date, informed consent and HIPAA Authorization from the subjects may be required.
- 3) Select “[] Columbia and/or NYP and “[] Data to be analyzed were or will be collected for clinical care” if all data come from CU/NYP medical records. In the generated field, please provide the specific patient eligibility criteria **AND** a list of variables that will be extracted by the study team **OR** requested in a TRAC report.
- 4) Select “Yes” to the field that asks if a member of the research team will be abstracting data directly from source documents. Complete the subsequently generated field that asks if you normally have access to the data as part of clinical care or if special authorization is needed. If special authorization is needed, please explain what approval will need to be sought or attach this approval to the protocol. Select “No” if data will be provided in report form as the result of a TRAC request.

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Status: Creating

records, etc.)
 Data originate from an IRB approved protocol
 Other
 Outside Columbia and/or NYP:

***Will a member of the research team be abstracting data directly from source documents ?**
 Yes No
 If there is a data abstraction document/spreadsheet, attach it to the submission to complete study records. Though the IRB does not approve these documents, for reference purposes they are extremely helpful in understanding the scope of the proposed data collection.
***Select the applicable responses:**
 The data, documents, or records to be reviewed/abstracted are those to which a member of the research team has legitimate access for non-research purposes (e.g., departmental patient database, physicians' patient clinical records, student records).
 Special authorization is necessary to review the records as the research team does not have access to the data, and a request will be or has been made to access the data.

***If any existing data was obtained from a prior research study, was any member of the current research team involved (e.g., obtained consent, performed study procedures, conducted data analysis) in the project or procedures that collected and/or used identifiable information?**
 Yes No N/A


***Indicate the manner in which the existing data and/or the records to be reviewed prospectively will be collected or received:** ⓘ
 (Select all that apply. At least one must be selected.)
 Contains direct identifiers (e.g., name, MRN, date of birth)
 Coded and the research team has the key and can link the data to direct identifiers
 Coded and the research team does not have access to the key to link data to direct identifiers
 Prior to the receipt of the data by the research team submitting this protocol, the identifiers will be removed and no link will remain. ⓘ
 The information was originally or will be collected without identifiers
 If data are collected or received at any point in time with direct identifiers or linked to identifiers, then the data are considered to be identifiable, and the requirements for Informed Consent (or a waiver, if applicable) and HIPAA Authorization (or a waiver, if applicable) apply. The necessary information will need to be included in the respective sections of the submission.

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 Please contact the Human Research Protection Office if you have questions about submitting to the IRB, or whether this study requires review.
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 (212) 305-5883 | irboffice@columbia.edu
 CUMS and LDCO Campus:
 (212) 851-7040 | asirb@columbia.edu

7746 Highlight All Match Case 1 of 1 match

- 1) As data are abstracted from medical records only, please update this field to indicate “N/A.; No data will come from a prior research study.”
- 2) This section refers to the manner in which data is received/accessed. As patient medical records contain direct identifiers, please update this field to select, “[x] Contains direct identifiers”.

****Tip:** Studies involving access to patient billing information will require approval from the CU Billing Compliance Office. They can be reached at billingcompliance@cumc.columbia.edu.

 **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-AAAR5752
Status: Creating

Abbreviated title	aa	Protocol Number	AAAR5752
Originating Department	OAD College and Arts & Scis (070350X)	Protocol Initiator	Rafael Santos (rs3275)
Protocol Year	1 Modification 00	Date Created	09/30/2017 10:17:38
Principal Investigator	Rafael Santos (rs3275)	You are	Rafael Santos (rs3275)

Future Use

*For what materials do you anticipate future research use? (Select all that apply.)

Data
 Biological Specimens

*Please indicate how data and/or specimens will be retained for future use: (Select all that apply.)

Some or all data and/or specimens, as applicable, will be retained by Columbia researchers for future use.

*How are the **materials** intended to be used for research in the future? [?](#)

Current PI will retain the materials and there is no intent to create a repository or share with other CU researchers. Note: Information provided in original consent forms will be considered when an addition of future uses is submitted via modification.
 Multiple researchers, which may include the current PI and research team, will be able to request use of the materials.

*What future uses are anticipated? [?](#)

*How will the data and/or specimens, as applicable, be labeled during storage for future uses.

In the same manner as during collection (e.g., with direct identifiers, coded, de-identified, anonymous) [?](#)
 In a different manner than during collection

*Describe the physical storage for the specimens/data, including location. [?](#)

In the same manner as during collection
 In a different manner than during collection

*Describe who will have access to the stored data and/or specimens.

Some or all data/specimens will be released to a non-Columbia entity for future use and Columbia researchers will not have direct control.

*Indicate to whom the data/specimens will be released

Sponsor
 Non-Columbia repository
 Other

*Describe plans for release of data and/or specimens. [?](#)

7746 Highlight All Match Case 1 of 1 match

- 1) If you previously indicated, “Yes” to the future use of data on the Procedures page, the page above will be subsequently generated. Please select, “[] Data”.
- 2) If you will retain the data at CUIMC, please select “[] Some or all data and/or specimens will be retained by Columbia researchers for future use” and complete the subsequently generated fields.
- 3) If data will be released externally, please select, “[] Some or all data/specimens will be released to a non-Columbia entity for future use and Columbia researchers will not have direct control.” Please identify the recipient and detail the confidentiality of the data transferred, as well as the data security utilized during transit.

**Note that transfer of data to an external site will likely require execution of a data use agreement. Please consult with CU SPA regarding the development/execution of a data use agreement prior to the transfer of data. The IRB just needs the final executed version prior to the data transfer.

IRB-AAAR5752
Status: Creating

Protocol Content

General Information

Attributes

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Coordinating Center

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Privacy & Data Security

Procedures

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Recruitment And Consent

Research Aims & Abstracts

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Protocol Actions

Abbreviated title	aa	Protocol Number	AAAR5752
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Principal Investigator	Rafael Santos (rs3275)	You are	Rafael Santos (rs3275)

Recruitment And Consent

Recruitment:

*Describe how participants will be recruited: ?

N/A - Retrospective chart review

*Select all methods by which participants will be recruited

Study does not involve recruitment procedures

Person to Person

Radio

Newspapers

Direct Mail

Website

Email

Television

Telephone

Flyer/Handout

Newsletter/Magazine/Journal

ResearchMatch

CUMC RecruitMe

Informed Consent Process: ?

*Informed Consent Process, Waiver or Exemption: Select all that apply

Informed consent with written *documentation* will be obtained from the research participant or appropriate representative.

Informed consent will be obtained but a waiver of written documentation of consent (i.e., agreement to participate in the research without a signature on a consent document) is requested.

A waiver of *some* or *all* elements of informed consent (45 CFR 46.116) is requested. ?

*Waiver of consent is applicable to:

The study in its entirety

A portion of the study or subject population

*Select the applicable situation:

This study qualifies for a waiver of consent as per 45CFR46.116(d) as the following criteria are met in this study (provide justification for EACH of these criteria):

*(1) The research involves no more than minimal risk to the subjects

Provide justification:

7746 Highlight All Match Case 1 of 1 match

- 1) As this is a retrospective chart review that involves no interaction with subjects, please update this section to indicate, "[x] Study does not involve recruitment procedures".
- 2) As this is a retrospective chart review that involves no interaction with subjects, please select, "[x] A waiver of some or all elements of informed consent is requested".
- 3) Please select, "[x] This study qualifies for a waiver of consent as per 45CFR46.116(d)."

RASCAL Human Subjects

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IRB-AABD7751
Status: Creating

Protocol Content

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Protocol Actions

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View Datasheet

- Tasks
- View Review Checklist
- Datasheet

A waiver of some or all elements of informed consent (45 CFR 46.116) is requested.

*Waiver of consent is applicable to:

- The study in its entirety
- A portion of the study or subject population

*Select the applicable situation:

This study qualifies for a waiver or alteration of consent as the following criteria are met in this study (provide justification for EACH of these criteria):

***(1) The research involves no more than minimal risk to the subjects**
Provide justification:

***(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects**
Provide justification:

***(3) The research could not practicably be carried out without the waiver or alteration**
Provide justification:

***(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation**
Provide justification:

(5) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format
****This waiver criterion does not apply if your research was initially approved before January 21, 2019, which is the general compliance date for the revised regulations at 45CFR46 subpart A.**
Provide justification:

This study qualifies for waiver or alteration of consent involving public benefit and service programs as the following criteria are met for this study (provide justification for EACH of these criteria):

- Planned Emergency Research with an exception from informed consent as per 21 CFR 31.24.
- This is exempt research

Subject Language

- Enrollment of non-English speaking subjects is expected.
- Enrollment of non-English speaking subjects is not expected.
- Language of subjects is unknown/irrelevant (e.g., record reviews, mass mailing of surveys)

Capacity to Provide Consent

Do you anticipate using surrogate consent or is research being done in an adult population where capacity to consent may be questionable?

Yes No

- 1) Please justify how each of the regulatory criteria are satisfied. It is not sufficient to simply state, “retrospective record review”. Please note that while the fifth justification may appear as an optional field, it is required for all studies submitted on or after January 21, 2019.
- 2) Please select, “[x] Language of subjects is unknown/irrelevant”.
- 3) Please indicate, “No” to the field that asks if surrogate consent is proposed.

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-AAAR5752
Status: Creating

Protocol Content

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Departmental Approvers

- Privacy & Data Security
- Procedures
- Existing Data
- Future Use
- Recruitment And Consent
- Research Aims & Abstracts**
- Risks, Benefits & Monitoring
- Subjects
- Child Involvement

Attachments

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Protocol Actions

- Notify Approvers

Research Aims & Abstracts

*Research Question(s)/Hypothesis(es):

*Scientific Abstract:

*Lay Abstract:

Find in page | Highlight All | Match Case

- 1) Please complete all fields found on this page. Note that it is not sufficient to refer to a standalone protocol in these fields. Please utilize the blue question mark icon for information about what is needed in each field.

IRB-AAAR5752
Status: Creating

Risks, Benefits & Monitoring

Abbreviated Submission:
The IRB has an abbreviated submission process for multicenter studies supported by industry or NIH cooperative groups (e.g., ACTG, HVTN, NCI oncology group studies, etc.), and other studies that have a complete stand-alone protocol. The process requires completion of all Rascal fields that provide information regarding local implementation of the study. However, entering study information into all of the relevant Rascal fields is not required, as the Columbia IRBs will rely on the attached stand-alone (e.g., sponsor's) protocol for review of the overall objectives.

If you select the Abbreviated Submission checkbox and a section is not covered by the attached stand-alone protocol, you will need to go back and provide this information in your submission.

Potential Risks:
Provide information regarding all risks to participants that are directly related to participation in this protocol, including any potential for a breach of confidentiality. Risks associated with any of the items described in the Procedures section of this submission should be outlined here if they are not captured in a stand-alone protocol. Risks of procedures that individuals would be exposed to regardless of whether they choose to participate in this research need not be detailed in this section, unless evaluation of those risks is the focus of this research. When applicable, the likelihood of certain risks should be explained and data on risks that have been encountered in past studies should be provided.

Abbreviated Submission - This information is included in an attached stand-alone protocol.

Risk of a breach in confidentiality

Potential Benefits:
Provide information regarding any anticipated benefits of participating in this research. There should be a rational description of why such benefits are expected based on current knowledge. If there is unlikely to be direct benefit to participants/subjects, describe benefits to society. Please note that elements of participation such as compensation, access to medical care, receiving study results, etc. are not considered benefits of research participation.

Abbreviated Submission - This information is included in an attached stand-alone protocol.

No direct benefit

- 1) Select “[x] Abbreviated Submission” only if you have a separate standalone protocol that includes the relevant information.
- 2) The Potential Risks section should include the potential for a breach in confidentiality.
- 3) The Potential Benefits section should state that subjects will likely receive no direct benefit. This section may include potential benefits to future populations.

IRB-AAAR5752
Status: Creating

Subjects

Unless otherwise noted, the information entered in this section should reflect the number of subjects enrolled or accrued under the purview of Columbia researchers, whether at Columbia or elsewhere. Definitions for Subjects, Enrollment, and Accrual can be found in the Help Text.

*Target enrollment:

*Number anticipated to be enrolled in the next approval period:

*Does this study involve screening/assessment procedures to determine subject eligibility?
 Yes No

*Is this a multi-center study?
 (Note: This question and the answer displayed below are on the Attributes page and may not be changed here. Display only.)
 Yes
 *Target number of eligible subjects to be included at all sites:

*Does this study have one or more components that apply to a subset of the overall study population (e.g. Phase 1/2, sub-studies)?
 Yes No

Target Enrollment Demographics:

*Population Gender
 Females Males Non-Specific

*Population Age
 0-7 8-17 18-65 >65 Non-Specific

*Population Race
 American Indian/Alaskan Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than One Race Non-Specific

*Population Ethnicity
 Hispanic or Latino Not Hispanic or Latino Non-Specific

Vulnerable Populations as per 45 CFR 46:

*Will children/minors be enrolled?
 Yes No

- 1) The target enrollment number should reflect the number of subjects you anticipate including in your analysis (e.g., the number of patient records accessed).
- 2) Only indicate, "Yes" to this field if you anticipate reviewing multiple records to determine eligibility of a subset of the total records accessed. If yes, please be sure that the target accrual number is lower than the target enrollment.
- 3) Please include your demographics. If you do not have specific targets for any field, please indicate "100% Non-Specific"

IRB-AAAR5752
Status: Creating

Population Ethnicity
 Hispanic or Latino: 0%
 Not Hispanic or Latino: 0%
 Non-Specific: 100%

Vulnerable Populations as per 45 CFR 101.116

*Will *children/minors* be enrolled? [?](#)
 Yes No

Note that upon "Save", you will see a link to the required "Child Involvement" page in the left side navigation menu. You must complete this page prior to submission.

*Will *pregnant women/fetuses/neonates* be targeted for enrollment? [?](#)
 Yes No

*Will *prisoners* be targeted for enrollment? [?](#)
 Yes No

Other Vulnerable Populations: [?](#)

- Individuals lacking capacity to provide consent
- CUNY/PH Employees/Residents/Fellows/Interns/Students
- Economically disadvantaged
- Educationally disadvantaged
- Non-English speaking
- Other
- None of the Populations listed above will be targeted for Enrollment

*Subject Population Justification: [?](#) 0 / 1000

*Does this study involve compensation or reimbursement to subjects?
 Yes No

Save

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Please contact the Human Research Protection Office if you have questions about submitting to the IRB, or whether this study requires review.
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 CU-MS and LDCO Campus:
 (212) 851-7040 | asiro@columbia.edu

Find in page | Highlight All | Match Case

1) Please identify any vulnerable population whose medical records will be utilized in the study.

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.

*Select the option below that best describes your study.

- No more than Minimal Risk (45 CFR 46.404/21 CFR 50.51; i.e., 'Section 404')
- Greater than 'Minimal Risk' with the prospect of direct benefit to the subjects. (45 CFR 46.405/21 CFR 50.52; i.e., 'Section 405')
- Greater than 'Minimal Risk' with NO prospect of direct benefit to the subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. (45 CFR 46.408/21 CFR 50.53; i.e., 'Section 408')
- Research not included in one of the above categories but which otherwise presents an opportunity to understand, prevent or alleviate a serious problem affecting the health and welfare of children. (45 CFR 46.407/21 CFR 50.54; i.e., 'Section 407')

*Explain how the risks of the research are minimal. '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.

Explain how the risks of the research are minimal

WARDS AND FOSTER CHILDREN

*If 'Section 406' or 'Section 407' research was indicated, the inclusion of wards or foster children requires additional information and, if the research will be conducted in New York City (NYC), approval from the NYC Administration for Children's Services (ACS). Please select the appropriate option below.

- This research has not been categorized as 45 CFR 46.406 ('Section 406') or 45 CFR 46.407 ('Section 407').
- This research has been categorized as 45 CFR 46.406 ('Section 406') or 45 CFR 46.407 ('Section 407') but the enrollment of wards or foster children is not anticipated.
- This research has been categorized as 45 CFR 46.406 or 45 CFR 46.407 and the enrollment of wards and/or foster children is anticipated.

ASSENT OF SUBJECTS

Assent of the child is required except in limited circumstances. The first step in determining whether assent is required and/or appropriate is to assess whether the children who will participate in the study will be capable of providing assent. The next step is to determine, for children who are capable of providing assent, whether assent will be obtained or should be waived.

*Indicate whether the children who will be enrolled in this study will generally be capable of providing assent.

- Some or all are expected to be capable of providing assent.
- None are expected to be capable of assent.

*Please explain why some or all of the children are expected to be capable of providing assent, and if applicable, why some may not be capable.

Please explain why some or all of the children are expected to be capable of providing assent, and if applicable, why some may not be capable

*For the children who are capable of providing assent, indicate whether you propose to obtain assent or to request a waiver of the requirement to obtain assent.

- A waiver of assent for children who are capable of providing assent is requested.
- Assent will be obtained from children who are capable of providing voluntary and informed agreement to participate.

*Indicate the waiver criteria that are most applicable to the research.

- The research presents the prospect for direct benefit that is important to the health or wellbeing of the children and is available only in the context of the research.
- Each of the following apply (45 CFR 46.116(d)):
 - The research involves no more than Minimal Risk; and
 - The Waiver will not adversely affect the rights and welfare of the subjects; and
 - The research could not practically be carried out without the waiver; and
 - The subjects will be provided with additional pertinent information when appropriate.

*Provide justification for each of these criteria

Provide justification for each of these criteria

PARENT/GUARDIAN PERMISSION

Permission of parents/guardians of the children is required except in limited circumstances. Permission from one parent/guardian is acceptable for research categorized as Section 404 or Section 405 unless waiver of informed consent is approved or the IRB determines that permission from both parents is warranted.

*Select the parental permission option that applies to your study, and provide the rationale for your response if justification is requested. For most studies, one selection is appropriate, however, if more than one option applies, select all that apply.

- The permission of one parent/guardian will be obtained.
- The permission of both parents/guardians will be obtained. - THIS IS REQUIRED IF YOU HAVE CATEGORIZED YOUR RESEARCH AS 45 CFR 46.406 OR 45 CFR 46.407
- No parental permission will be obtained because each of the following waiver criteria for waiving parental permission apply (45 CFR 46.408(c)).
- No parental permission will be obtained because the involvement of children in this research meets the criteria for a complete waiver of consent (45 CFR 46.116(d)), which is requested in the 'Recruitment and Informed Consent' section.

- 1) If you previously indicated on the Subjects page that children/minors will be enrolled, the subsequently generated page shown above will appear. Please select 'No more than Minimal Risk (45 CFR 46.404/21 CFR 50.51; i.e., 'Section 404')
- 2) Under Wards and Foster Children, please select 'This research has not been categorized as 45 CFR 46.406 ('Section 406') or 45 CFR 46.407 ('Section 407').'
- 3) Children ages 7-17 are generally considered to be capable of providing assent. If you anticipate including charts from children ages 7-17, please indicate 'Some or all are expected to be capable of provided assent' and then select 'A waiver of assent for children who are capable of providing assent is requested.'
- 4) Under Parental/Guardian Permission, select 'No parental permission will be obtained because the involvement of children in this research meets the criteria for a complete waiver of consent''

RASCAL Human Subjects

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Abbreviated title	aa	Protocol Number	AAAR6752
Originating Department	OAD College and Arts & Scis (070350X)	Protocol Initiator	Rafael Santos (rs3275)
Protocol Year	1 Modification 00	Date Created	09/30/2017 10:17:38
Principal Investigator	Rafael Santos (rs3275)	You are	Rafael Santos (rs3275)

HIPAA Forms

Help

Current Attached HIPAA Forms

HIPAA Number	Type	Title	Status
No data to display			

All released HIPAA Forms to which you have access and are not currently attached to a protocol.

HIPAA Number	Type	Title	Status	Attach
HIPAA-AAA01721	Form B: Application for Waiver of Authorization	RS	Create	

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 CUMC Campus: [www.cumc.columbia.edu](#)
 P&S Campus: [www.pandps.columbia.edu](#)

Attachments

- Hazmats
- HIPAA Forms**
- Documents
- Consent Form

Protocol Actions

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Protocol View

- Print Menu
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- View History

Find in page | Highlight All | Match Case

- 1) Please create a HIPAA Form B (Waiver of Authorization) within the HIPAA Forms module in Rascal. Please ensure that the justification provided for each of the criteria is consistent with what is described in the protocol. Please also ensure that item #2 explicitly indicates when PHI will be destroyed (e.g. at the conclusion of the research) and that item #3 explicitly indicates that no reuse/disclosure of PHI will take place, unless there are plans described within the protocol for future use/disclosure of PHI.
- 2) Please access the HIPAA Forms link within your protocol and attach/submit the HIPAA Form B.

RASCAL Human Subjects

Personnel

Abbreviated title	aa	Protocol Number	AAAR5752
Originating Department	OAD College and Arts & Scis (070350X)	Protocol Initiator	Rafael Santos (rs3275)
Protocol Year	1 Modification 00	Date Created	09/30/2017 10:17:38
Principal Investigator	Rafael Santos (rs3275)	You are	Rafael Santos (rs3275)

Notify Approvers

Click on one of the buttons below to Notify Approvers.

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Please contact the Human Research Protection Office if you have questions about submitting to the IRB, or whether this study requires review:
 CUMC Campus:
 (212) 305-5883 | irboffice@columbia.edu
 CU-MS and LDEO Campus:
 (212) 851-7040 | askirb@columbia.edu

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- 1) Select “Notify Approvers”
- 2) Once all staff have approved, you will be able to submit to the IRB by selecting the “Submit Protocol link”.

****Tip:** Access the Protocol Overview page to ensure that the study status has changed from “Creating” to “Submitted”.