

Columbia University Human Subjects Protocol Data Sheet

General Information

Protocol:	AABB6850(M00Y01)	Protocol Status:	Creating
Effective Date:		Expiration Date:	
Originating Department Code:		PSY Exper Therap General (7543501)	
Principal Investigator:		Ruotolo, Brenda (blr2102)	
From what Columbia campus does this research originate:		Medical Center	
Title:	BLR Test Protocol 1		
Protocol Version #:	V1	Abbreviated Title:	BLR1
Was this protocol previously assigned a number by an IRB:		Yes	
Previous Columbia IRB#:		Previous External IRB#:	8888

Is the purpose of this submission to obtain a "Not Human Subjects Research" determination?

No

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

Select the most appropriate response:

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.

Provide the names of the non-Columbia institution(s) that will rely on the Columbia IRB.

NYSPI

Does this study meet the criteria for an existing IRB Authorization Agreement (IAA)?

Yes

Select the applicable IAA from the list.

New York State Psychiatric Institute

Is this research part of a multicenter study?

Yes

Indicate Columbia's involvement by checking all applicable roles below

☒ Columbia is a study site

Does this submission describe and seek approval for the study procedures at Columbia?

Yes

- ☐ Columbia is the Lead Institution
- ☐ Columbia is serving as the Clinical Coordinating Center
- ☐ Columbia is serving as the Data Coordinating Center
- ☐ Columbia is serving as the site for a repository of biological specimens related to this study

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

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 description 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. Proceed to the next question

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. Proceed to the next question

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. Proceed to the next question

Exempt and Expedited

Is the purpose of this submission to obtain an exemption determination, in accordance with 45CFR46.101(b):

No

Is the purpose of this submission to seek expedited review , as per the federal categories referenced in 45CFR46.110?

No

Funding

Is there any external funding or support that is applied for or awarded, or are you the recipient of a gift, for this project?

No

Locations

Location Type	Facility Name	Domestic or International	Geographic Location	Local IRB Ethics Approval	Local Site Approval
Offsite	NYSPI	Domestic	New York	Yes	No, approval is not required

Personnel

UNI/Phone	Name	Role	Department	Edit/View	Obtaining Informed Consent
blr2102 212-342-1218	Ruotolo, Brenda	Principal Investigator	RES Institutional Review Board (0912102)	Edit	Y
Roles and Experience: djakdlj					

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 you may be required to take, visit the [Research Compliance Training Finder](#).

UNI	Name	COI	HIPAA	HSP (CITI)	Research with Minors (CITI)	FDA-Regulated Research (CITI)	Sponsor-Investigator	CRC
blr2102	Ruotolo, Brenda	01/18/2023						

Departmental Approvers

Privacy & Data Security

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

☐ Hardcopy (i.e., paper)

☒ Electronic

Where will the data be stored?

Y

☒ On a System

☐ On an Endpoint

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

Yes

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?

☒ 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 the System ID numbers for the certified environment in which the Sensitive Data will be stored

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☐ Sensitive data will be stored on an encrypted endpoint

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):

See PSF

If your project is not NIH funded, has a Certificate of Confidentiality (CoC) been requested for this research?

No

Provide a description of the protections in place to safeguard participants' privacy while information is being collected:

See PSF

Procedures

Is this project a clinical trial?

Yes

Is this project a clinical trial that requires registration with www.clinicaltrials.gov?

Yes

Has this study been registered with www.clinicaltrials.gov?

Yes

Please provide the registration number:

dfddf

Is this project associated with, or an extension of, an existing Rascal protocol?

No

Do study procedures involve any of the following?

Analysis of existing data and/or prospective record review

No

Audio, video or photographic recording of research subjects

No

Behavioral Intervention?

Yes

Biological specimens (collection or use of)

Yes

Cancer-related research

No

Drugs or Biologics

Yes

Future use of data and/or specimens

No

Genetic research

No

Home Visits

No

Human Embryonic and/or Human Pluripotent Stem Cells

No

Imaging procedures or radiation

Yes

Medical Devices

No

Surgical procedures that would not otherwise be conducted or are beyond standard of care

No

Will any of the following qualitative research methods be used?

Survey/interview/questionnaire

Yes

NOTE: You must attach a PDF version of the survey(s)/interview(s)/questionnaire(s) to this protocol prior to submission.

Systematic observation of public or group behavior

No

Program evaluation

No

Will any of the following tests or evaluations be used?

Cognitive testing

Yes

Educational testing

No

Non-invasive physical measurements

No

Taste testing

No

Is there a stand-alone protocol that describes ALL procedures in this study?

Yes

[x]Check here if all procedures being conducted by Columbia researchers are detailed in the stand-alone protocol, or provide a detailed description of which procedures are being conducted by Columbia researchers.

Biological Specimens

Add an individual entry for each human specimen type that will be collected or utilized for the proposed study. For each specimen type, indicate the source or sources from which you will obtain the specimens.

The use of specimens for research purposes may require that informed consent (or a waiver, if applicable) and HIPAA Authorization (or a waiver, if applicable) be obtained from subjects.

Drugs/Biologics

On the General Information page you have indicated that the protocol version associated with the use of this drug/biologic is as follows: V1

Please note that a Protocol Version # is required for protocols using a drug or biologic, and you will not be allowed to submit this protocol until the Protocol Version # field is complete. Please ensure that the Protocol Version # is completely and accurately reported on the General Information page.

List each drug or biologic that will be administered as the object of the protocol or is being used because it is relevant to the aims of the research protocol. This applies whether the drug/biologic is not yet FDA-approved (i.e., is investigational), is FDA approved and used in accordance with its labeling, or is an approved product that is being used in an investigational manner (i.e., off-label use is being studied).

Note that the questions apply only to drugs used in clinical investigations. Emergency use of a drug that is not yet FDA-approved is not a clinical investigation, and a submission in Rascal may not be required. Please contact the IRB for assistance if emergency use of a drug or biologic that is not yet FDA-approved is being considered: (212) 305-5883.

Imaging Procedures/Radiation Therapy

For each type of radiation exposure (e.g., ionizing: CT, X-ray; non-ionizing: MRI), identify the procedure and whether the administration (e.g., radiation dosage, number or type of scans) is clinically indicated and in accordance with the parameters established for the applicable standard of care (SOC), or is "beyond" these parameters (i.e., includes procedures or exposure for research purposes only).

Recruitment And Consent

Research Aims & Abstracts

Research Question(s)/Hypothesis(es):

Scientific Abstract:

Lay Abstract:

Risks, Benefits & Monitoring

Abbreviated Submission:

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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.

[x] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

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.

[x] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

Alternatives:

If this research involves an intervention that presents greater than minimal risk to participants, describe available alternative interventions and provide data to support their efficacy and/or availability. Note, participants always have the option not to participate in research.

[x] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

Data and Safety Monitoring:

Describe how data and safety will be monitored locally and, if this is a multi-center study, how data and safety will be monitored across sites as well.

[x] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

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.

Target enrollment:

Number anticipated to be enrolled in the next approval period:

Does this study involve screening/assessment procedures to determine subject eligibility?

Is this a multi-center study?

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)?

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****Will pregnant women/fetuses/neonates be targeted for enrollment?****Will prisoners be targeted for enrollment?****Other Vulnerable Populations:**☐ Individuals lacking capacity to provide consent☐ CU/NYPH Employees/Residents/Fellows/Interns/Students☐ Economically disadvantaged☐ Educationally disadvantaged☐ Non-English speaking☐ Other Vulnerable populations☐ None of the Populations listed above will be targeted for Enrollment**Subject Population Justification:****Does this study involve compensation or reimbursement to subjects?****Documents**

Archived	Document Identifier	Document Type	File Name	Active	Stamped	Date Attached	Created By
No	PSF 8888	Standalone/Sponsor's Protocol	2023-07-01_FY24_BLR_attendance tracking.xlsx	Y	No	08/18/2023	Brenda Ruotolo (blr2102)

Tasks