
Protocol Title

Test Study

Protocol Number

5570

First Approval

N/A

Expiration Date

Not yet accepted

Principal Investigator:

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Co-Investigator(s):

Thomas Edison

Faculty Sponsor:

Charles Darwin

Cover Sheet

Select from the following that are applicable to your study

- ✓ I am submitting a new protocol
- ✓ I am proposing an amendment to an existing protocol
- ✓ I am submitting a continuation/5 year renewal

Amendment

Describe the change(s) being made

Provide the rationale for the change(s)

Comment on the extent to which the proposed change(s) alter or affect risks/benefits to subjects

Comment on if the proposed change(s) require a modification to the Consent Form (CF)

Application for Continuation of Research

Status

Current Status of Study:

Funding

Have there been any changes in funding status since the prior approval?

Have the principal investigator and other investigators made all required disclosures of financial interest in the study sponsor/product?

Summary

Have there been any study findings, recent literature, or untoward events occurring here or at other sites in the past year which might affect the analysis of the safety, risks or benefits of study participation?

Have all study staff with a significant role in the design or implementation of the human subject components of this study received required training in human research subject protections?

Is the study covered by a certificate of confidentiality?

Approved Sample and Progress

Approved sample size

Total number of subjects studied since first approval

Have there been any significant deviations from the anticipated study completion estimates?

Comments / additional information

Procedures

To create the protocol summary form, first indicate if this research will include any of the following procedures

- ✓ Quality Improvement/Program Evaluation Only
- ✓ Psychiatric Assessment
- ✓ Neuropsychological Evaluation
- ✓ Collection of Biological Specimens
- ✓ Lumbar Puncture
- ✓ Studies of DNA
- ✓ Use of Stem Cells
- ✓ Medication Trial
- ✓ Use of Placebo or Sham Treatment
- ✓ Psychotherapy Trial
- ✓ PET/SPECT Scan
- ✓ MRI
- ✓ Biological Challenge Procedure
- ✓ Medication-Free Period or Treatment Washout

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- ✓ Administration of Substance of Abuse
 - ✓ Arterial Line
 - ✓ Audio or Videotaping
 - ✓ Device Trial
 - ✓ Use of Investigational Drug or Device
 - ✓ Off-label Use of Drug or Device
 - ✓ Somatic Treatment or Intervention
 - ✓ Internet-based Data Collection or Transmission

Population

Indicate which of the following populations will be included in this research

- ✓ Adults who may have impaired decision-making ability
- ✓ Adults who lack capacity to consent
- ✓ Prisoners
- ✓ Pregnant Woman
- ✓ Children (to age 7)
- ✓ Children (ages 8-12)
- ✓ Children (ages 13-17)
- ✓ Medically Ill Subjects
- ✓ Medically and Psychiatrically Healthy Subjects
- ✓ Adults
- ✓ Adults over 50
- ✓ Employees or Students
- ✓ Individuals with HIV/AIDS
- ✓ Non-English Speaking Participants
- ✓ Substance Users
- ✓ Individuals with Psychosis
- ✓ Acutely Manic Individuals
- ✓ Inpatients
- ✓ Involuntarily Committed Patients

Research Support/Funding

Will an existing internal account be used to support the project?

Yes

Describe internal account

Is the project externally funded or is external funding planned?

Yes

Select the number of external sources of funding that will be applicable to this study

1

Funding Source #1

Is the PI of the grant/contract the same as the PI of the IRB protocol?

Select one of the following

Source of Funding

Select one of the following

Business Office

Does the grant/contract involve a subcontract?

Study Location

Indicate if the research is/will be conducted at any of the following

- ✓ NYSPI
- ✓ Washington Heights Community Service
- ✓ Other Columbia University Medical Center Facilities

This protocol describes research conducted by the PI at other facilities/locations

Yes

- ✓ Office of Mental Health facilities
- ✓ Hospital, clinics and other healthcare facilities
- ✓ Schools/Educational Institutions
- ✓ Prison system
- ✓ International Sites
- ✓ Other Facilities
- ✓ Community Sources

Office of Mental Health facilities

Select from the list
or type in location(s)..

Will you be applying for an OMH multisite agreement with NYSPI as the sole reviewing IRB?

Hospitals,clinics and other healthcare facilities

Select from the list
or type in location(s)..

Schools/Educational Institutions

Type in location(s)

Prison System(Includes Parole)

Type in location(s)

International Sites

Type in location(s)

Other Facilities

Type in location(s)

Community Sources

Type in location(s)

Lay Summary of Proposed Research

Lay Summary of Proposed Research

Background, Significance and Rationale

Background, Significance and Rationale

Specific Aims and Hypotheses

Specific Aims and Hypotheses

Description of Subject Population/Justification for Subject Selection

Select the number of samples that will be required for this study

4

Sample #1

Specify subject population

Number of completers required to accomplish study aims

Projected number of subjects who will be enrolled to obtain required number of completers

Age range of subject population

Sample #2

Specify subject population

Number of completers required to accomplish study aims

Projected number of subjects who will be enrolled to obtain required number of completers

Age range of subject population

Sample #3

Specify subject population

Number of completers required to accomplish study aims

Projected number of subjects who will be enrolled to obtain required number of completers

Age range of subject population

Sample #4

Specify subject population

Number of completers required to accomplish study aims

Projected number of subjects who will be enrolled to obtain required number of completers

Age range of subject population

Gender and Ethnic Breakdown

Description of subject population

Recruitment Procedures

Describe settings where recruitment will occur

How and by whom will subjects be approached and/or recruited?

How will the study be advertised/publicized?

Do you have ads/recruitment material requiring review at this time?

Concurrent Research Studies

Will subjects in this study participate in or be recruited from other studies?

Inclusion/Exclusion Criteria

Select the number of subjects groups or sub samples for which you will describe separate inclusion and exclusion criteria

3

Name the subject group/sub sample

Create or insert table to describe the inclusion criteria and methods to ascertain them

Create or insert table to describe the exclusion criteria and methods to ascertain them

Inclusion/Exclusion Criteria #2

Name the subject group/sub sample

Create or insert table to describe the inclusion criteria and methods to ascertain them

Create or insert table to describe the exclusion criteria and methods to ascertain them

Inclusion/Exclusion Criteria #3

Name the subject group/sub sample

Create or insert table to describe the inclusion criteria and methods to ascertain them

Create or insert table to describe the exclusion criteria and methods to ascertain them

Waiver of Consent/Authorization

Indicate if you are requesting any of the following consent waivers

Waiver of consent for use of records that include protected health information (a HIPAA waiver of Authorization)

Yes

Waiver or alteration of consent

Yes

Waiver of documentation of consent

Yes

Waiver of parental consent

Yes

Consent Procedures

Is eligibility screening for this study conducted under a different IRB protocol?

Describe Study Consent Procedures

Indicate which of the following are employed as a part of screening or main study consent procedures

- ✓ Consent Form
- ✓ Information Sheet
- ✓ Consent Script

Waiver of Consent for use of Protected Health Information

What records do you wish to review?

What information are you seeking access to?

Describe your plan to protect identifiers from improper use and disclosure

Describe your plan to destroy the identifiers as soon as possible consistent with the conduct of the research, or provide a health or research justification for retaining the identifiers or explain how retention is required by law

Explain why the research could not be practicably carried out without the information (for which you are requesting access)

Explain why the research cannot be practicably carried out without the waiver

Explain how/if subjects will be provided with additional pertinent information after participation

Justification for Waiver or Alteration of Consent

Waiver of consent is requested for the following

Explain why your research can not be practicably carried out without the waiver or alteration

Describe whether and how subjects will be provided with additional pertinent information after participation

Waiver of Documentation of Consent

Would the consent form signature be the only link between the subject's identity and the research data?

Is breach of confidentiality the main study risk?

Waiver of Parental Consent

Explain why parental/guardian consent is not a reasonable requirement to protect the minor participants in this study

If parental consent is waived, describe a mechanism that will be substituted to provide

appropriate protections for the subjects

Assent Procedures

Describe procedures by which subject assent will be assessed and/or recorded

Persons designated to discuss and document consent

Select the names of persons designated to obtain consent/assent
Type in the name(s) not found in the above list

Independent Assessment of Capacity

You have indicated that your study involves subjects who **MAY LACK** capacity to consent.
Does this study require an independent assessment of capacity?

You have indicated that your study involves subjects who **DO LACK** capacity to consent.

Please justify

Procedures for surrogate consent

Study Procedures

Describe the procedures required for this study

You can upload charts or diagrams if any

Criteria for Early Discontinuation

Criteria for Early Discontinuation

Blood and other Biological Samples

Please create or insert a table describing the proposed collection of blood or other biological specimens

Assessment Instruments

Create a table or give a brief description of the instruments that will be used for

assessment

Please attach copies, unless standard instruments are used

Off label and investigational use of drugs/devices

Choose from the following that will be applicable to your study

- ✓ Drug
- ✓ Device
- ✓ Radiolabeled drug/compound

Select the number of drugs used in this study

1

Drug #1

Name of the drug
Manufacturer and other information
Approval Status

Off label and investigational use of devices

Device #1

Name of the device
Manufacturer and other information
Approval Status

Off label and investigational use of radiolabeled drugs/compounds

Radiolabeled Drug/Compound #1

Name of the radiolabeled drug/compound
Manufacturer and other information
Approval Status

Research Related Delay to Treatment

Will research procedures result in a delay to treatment?
Treatment to be provided at the end of the study

Clinical Treatment Alternatives

Clinical treatment alternatives

Risks/Discomforts/Inconveniences

Risks that could be encountered during the study period
Describe procedures for minimizing risks

Methods to Protect Confidentiality

Describe methods to protect confidentiality
Will the study be conducted under a certificate of confidentiality?

Direct Benefits to Subjects

Direct Benefits to Subjects

Compensation and/or Reimbursement

Will compensation or reimbursement for expenses be offered to subjects?

References

References

Uploads

Upload the complete grant application(s)

Upload copy(ies) of Consent Form(s)

Upload copy(ies) of Information Sheet(s)

Upload copy(ies) of Consent Script(s)

Upload copy(ies) of Assent Form(s)

Please forward a letter from the Director of the Washington Heights Community Service indicating approval of the recruitment and/or study of patients from that site.

Upload any additional documents that may be related to this study