

How to create and submit a new Protocol/5 year renewal

Log in to PRISM (<https://irb.nyspi.org/prism>) using your IRB website username and password.

1. From the Home tab, click on ‘Start A Draft Protocol or 5 Year Continuation’

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Marie Cur [log] Prims 1.

Home My Studies Forms

Options

- IRB Messages
- **START A DRAFT PROTOCOL OR 5 YEAR CONTINUATION**
- PRISM FAQs

IRB Messages

There are no messages from the IRB at this time.

2. Give your protocol a title, give yourself a role and define the research team (i.e. Investigators/research staff who will be working on the study). Click on ‘Open protocol’ to create the protocol and open a blank Protocol Summary Form (PSF).

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Options

- IRB MESSAGES
- **Start A Draft Protocol Or 5 Year Continuation**
- PRISM FAQs

Draft Protocol

PROTOCOL TITLE

RESEARCH TEAM

Please add the Principal Investigator and any research staff who will need to access this system. Only staff who have completed Citi Training for NYSPI will be listed here.

Investigator	Role	Edit	Delete

Add Members:

Personnel: abdul, kazeem

Role: --

Add

OVERSIGHT

Role	Personnel	Edit	Delete
Faculty Sponsor	None		
Research Chief	None		

Add Oversight:

Personnel: abdul, kazeem

Role: --

Add

E-MAIL CONTACT(S)

Alternate staff contacts

open protocol

3. On the cover sheet, choose ‘I am submitting a new protocol’ if it a new study. Choose ‘I am submitting a 5 year renewal’ if it is a 5 year continuation

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Protocol Summary Form - Test Study
Protocol #: 5570

Role of Current User: Principal Investigator

Current Status: In Development

Cover Sheet

Choose **ONE** option from the following that is applicable to your study

- I am submitting a new protocol
- I am proposing an amendment only to an existing protocol
- I am submitting an annual continuation only
- I am submitting an annual continuation with a modification
- I am submitting a 5 year renewal

I have completed this page

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[Population](#)
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4. In order to generate the full PSF, you must indicate the procedures and populations that are involved in the proposed research. Answer all questions on each page, remembering to check off the “I have completed this page” box at the bottom of each page when you are finished. Please note that you can always save your work and return to the form at another time.

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Protocol Summary Form - Test Study
Protocol #: 5570

Role of Current User: Principal Investigator

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Procedures

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

- Secondary Data Analysis Only
- Closed Record/Chart Review Only
- 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
- Any Use of Ionizing Radiation(other than PET/SPECT Scan)
- MRI
- Biological Challenge Procedure
- Medication-Free Period or Treatment Washout
- 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
- None of those listed

I have completed this page

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5. Use the 'Go to Page' menu on the right-hand side to navigate through the form. Once you complete the Survey Completion Confirmation page, you will notice that a number of new pages have been added to the form. These pages and questions are tailored to the research you described on the Procedures and Populations pages, thus all questions are applicable and required.

6. Use the features of the editor (the grey toolbar at the top of the textbox) to format, modify or highlight any text, if required.

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Protocol Summary Form - Test Study
Protocol #: 5570

Role of Current User: Principal Investigator
Current Status: In Development

Lay Summary of Proposed Research

Lay Summary of Proposed Research

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- Cover Sheet
- Division & Personnel
- Procedures
- Population
- Survey Completion Confirmation
- Research Support/Funding
- Study Location
- Lay Summary of Proposed Research**
- Background, Significance and Rationale
- Specific Aims and Hypotheses
- Description of Subject
- Population/Justification for Subject Selection
- Recruitment Procedures
- Concurrent Research Studies
- Inclusion/Exclusion Criteria
- Waiver of Consent/Authorization
- Consent Procedures
- Persons designated to discuss and document consent
- Study Procedures
- Assessment Instruments
- Research Related Delay to Treatment
- Risks/Discomforts/Inconveniences
- Methods to Protect Confidentiality
- Direct Benefits to Subjects
- Compensation and/or Reimbursement
- References
- Uploads
- Next Steps

Save Page in Progress I have completed this page

Send Form

7. After you have completed all pages, hit the “Send form” button to submit the application for Research Chief approval.

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Protocol Summary Form - Test Study Role of Current User: Research Chief

Protocol #: 5570 Current Status: Awaiting Research Chief Approval

Uploads

Note: The system currently accepts only pdf uploads. If you have any difficulty with uploading and converting your files, you can use [this](#) free software. If you are still experiencing difficulty, please contact the IRB Help Desk.

Note: During every submission of your form to the IRB, this page should include all of the parts of the complete document as you intend for the IRB to review it. Do not remove attachments or sections, previous to submission, unless you do not wish for them to be reviewed, approved and/or stamped.

Please do not upload your cover memo here. You will be asked to upload your cover memo before your form gets sent to the IRB.

Upload any additional documents that may be related to this study

No file chosen

No file chosen

No file chosen

No file chosen

No file chosen

No file chosen

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- [Lay Summary of Proposed Research](#)
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[Next Steps](#)

8. If you are the PI on the study, you will be able to view the following screenshot to submit your form for approval.

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Marie Curie
 [logout]
 Prism 1.0.0

Home | My Studies ² | Forms ²

PSF for 5570 (In Development - 9/13/2012) close x

Workflow Options <<form menu

The following options are currently available.

[Forward to Research Chief for initial approval \(ALL NEW PROTOCOLS & 5 YEAR RENEWALS\)](#)

	Expiration Date	PI	Protocol Manager
	12/15/2011	Cune, Marie	Drew Theodore Lipsky
	4/11/2012	Cune, Marie	Drew Theodore Lipsky
	none	Cune, Marie	Drew Theodore Lipsky
	none	Cune, Marie	Drew Theodore Lipsky
SION AMONG MEN IN SOUTH AFRICA	none	Cune, Marie	none

9. Complete the five steps listed below to submit the PSF to the Research Chief for approval.

Home | My Studies [?] | Forms [?]

PSF for 5570 (In Development - 9/13/2012) close [x]

Workflow Options <<form menu

Before you can proceed you must complete the following step(s):

1. Formal Memo
2. Verification
3. Attestation
4. Save in Archive
5. Notify Research Chief

Upload the memo.

(size limit of 4M)

[cancel](#)

Expiration Date	PI	Protocol Manager
12/15/2011	Curie, Marie	Drew Theodore Lipsky
4/11/2012	Curie, Marie	Drew Theodore Lipsky
none	Curie, Marie	Drew Theodore Lipsky
none	Curie, Marie	Drew Theodore Lipsky
TH AFRICA	Curie, Marie	none

10. Note that submission is not complete until you reach the following page.

Home | My Studies [?] | Forms [?]

PSF for 5570 (In Development - 9/13/2012) close [x]

Workflow Options <<form menu

Finished.
The Form status is now Awaiting Research Chief Approval

Expiration Date	PI	Protocol Manager
12/15/2011	Curie, Marie	Drew Theodore Lipsky
4/11/2012	Curie, Marie	Drew Theodore Lipsky
none	Curie, Marie	Drew Theodore Lipsky
none	Curie, Marie	Drew Theodore Lipsky
AMONG MEN IN SOUTH AFRICA	Curie, Marie	none