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| Description: Description: https://dl.dropboxusercontent.com/u/83124818/nyu_shanghai_logo.jpeg | New York University Shanghai**Research Compliance Office**  |

## APPLICATION FOR AMENDMENT

A study must be carried out in accordance with the protocol approved by the IRB. Any changes in the study, including (for example) changes in the subject population, recruitment plans, advertising materials, research procedures, instruments, sites or research personnel who are instrumental to the design or execution of the study must be approved by the IRB prior to the change taking place.

## Submission Instructions

Our website provides full instructions on submitting applications to the IRB: [http://shanghai.nyu.edu/research/resources](http://shanghai.nyu.edu/research/resources%22%20%5Ct%20%22_blank). Please contact the IRB office at RCOinfo@nyu.edu with any questions.

When submitting an *Application for Amendment*, you need only submit those documents that have been revised for review. For example: If you are revising an advertisement, you need only submit the advertisement.

[ ]  this completed form (Minus the instructions/first page)

[ ]  all current IRB approved documents that you seek to revise

[ ]  all revised documents **with changes highlighted**

[ ]  clean copies of all revised documents to be stamped with IRB approval (must be in MS Word format)

If you are adding or deleting research personnel, include documentation or a statement that they have completed all tutorial training requirements. Also include a CV for any changed principal or co-investigator.

***Instructions for submitting AMENDMENT APPLICATIONS*** *(changes to approved study protocols):*

*Submit to:* **RCOinfo@nyu.edu**

*In the subject line, write:* AMENDMENT to IRB#\_\_\_\_\_\_, Title: \_\_\_\_\_\_, PI Name \_\_\_\_\_\_\_

*In the body of the e-mail:*

List and number the contents of the attachments:

*Enclosed are the following attachments:*

*1) Amendment form (use MS Word only)*

*2) Revised consent documents (use MS Word only)*

*3) Revised research instrument (MS Word or PDF)*

*4) Scanned signature page of amendment form (PDF only)*

## Application for Amendment

## Administrative Information

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| Study# |       | Date of this request |       |
| Study Title |       |
| Department |       | School |       |
| Role\* | Name | NYU Email | Phone | Fax |
| Principal Investigator/Faculty Sponsor |       |       |       |       |
| Contact Person |       |       |       |       |
| Co-Investigators |       |       |       |       |
|       |       |       |       |       |
| \* PI and Contact Person are required; list all other study personnel as well, one line per person. Principal Investigators must be NYU faculty. |
| All personnel listed above have completed the [CITI](https://www.citiprogram.org/Default.asp?ref=new) | [ ]  Yes[ ]  NoIf not all personnel have completed training, the amendment cannot be approved until all personnel have completed training and notified the IRB. |
| Sponsor(s) (list all) |       |
| Research Type | [ ]  Faculty Research [ ]  Postdoctoral Research[ ]  Student Research: [ ]  Undergraduate [ ]  Graduate [ ]  Doctoral Dissertation |
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**Change(s)** Please provide a brief description of changes being made and include a clear rationale for the changes.

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| For NIH Funded Studies Only | [ ]  Changes involve [ ]  Do not involve any of the following:[ ] Change in Human Subjects Involvement, NIH Funded Research Requiring Prior NIH Approval (attach NIH required documentation for prior approval request) See NIH notice No. NOT-OD-12-129 at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-129.html>[ ] Change in NIH Funded Research Initially Submitted without Definitive Plans for Human Subjects Involvement Requiring Prior NIH Approval (attach NIH required documentation for prior approval request) See NIH notice No. NOT-OD-12-130 at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-130.html>Please refer to Amendment Appendix A: NIH Prior Approval Addiotional Documentation.Amendments that require NIH prior approval must be submitted to the NYU IRB for approval prior to submitting the request to the NIH. Please keep in mind that the NIH requires submission at least 30 days prior to the proposed change(s). The NYU IRB requests that you allow at least two months prior to the implementation of proposed changes to ensure that the committee and NIH have adequate review time. |
| Indicate all changes you are proposing to make | [ ] Changes in currently approved protocol (submit revised protocol application and all applicable attachments. Indicate revised sections of protocol in the “Brief description of changes being made” section above)[ ] Change(s) in currently approved consent form(s)[ ] Addition/Deletion of study personnel (non-PI/non-Co-PI)[ ] Change in Principal Investigator (Requires departmental/school approval)[ ] Change in Co-Principal Investigator[ ] Advertisement(s)/recruitment materials[ ] Addition/Deletion of a Site/sites[ ] Request Additional Study Subjects: Current Approved number:      plus additional study subjects number:       for a total number of       study subjects (provide justification in “Brief description of changes being made” section above or on a separate sheet)[ ]  Change in subject population (provide justification in “Brief description of changes being made” section above)[ ] Addition/Deletion of Sponsored Funding (attach grant proposal if adding funding source(s))[ ] Additional Information or forms (specify):      [ ] Other (specify):       |
| Check all that apply | [ ] This change does not increase risks to participants enrolled in the study[ ] This change may increase risks to participants enrolled in the study[ ] This change does not necessitate revision of the consent form document[ ] Subjects already enrolled will be re-consented |
| If the change may increase risks to participants enrolled in the study, explain why the change is necessary  |       for example, the change is proposed by the sponsor or a national group. Attach the sponsor's formal notice of a change or revised protocol, if applicable |

## PI/FACULTY SPONSOR Signature

|  |  |
| --- | --- |
| Date |       |
| Print Name |       |
| Signature | I ATTEST THAT THE INFORMATION CONTAINED HEREIN IS A TRUE AND ACCURATE REPRESENTATION OF MY OR MY STUDENT’S ONGOING STUDY |

## Department/School Signature

Only required if this amendment is a change of the Principal Investigator and/or required by the school or department.

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| Date |       |
| Print Name |       |
| Signature | I ATTEST THAT THE INVESTIGATOR ABOVE IS BOTH AUTHORIZED AND FULLY QUALIFIED TO TAKE ON THE ROLE OF PRINCIPAL INVESTIGATOR FOR THE STUDY |

## IRB Approval (official use only)

|  |  |  |  |
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| IRB# |       | Date of review:       | IRB Signature:       |
| Approval Period  | From:       To:       (must not exceed annual review date) |