**REQUEST FOR CONTINUING REVIEW**

Version 03.2022

**Please refer to**

**PI:*****Name:***

***Address****:*

***Email****:* ***Phone Number:***

**Please indicate your Rutgers institutional status: Faculty**: [ ] **Staff**:[ ] **Student**:[ ]

**Study Contact person** (i.e., person who prepared submission *if* different than PI):

**Study Contact person's phone number:**

**Study Contact person’s E-mail address:**

**IRB #** **EXPIRATION DATE:**

**TITLE:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Federal regulations and university policy require that all expedited and full-board IRB-approved

 research be reviewed at least annually by the Institutional Review Board (IRB).

**Incomplete responses may delay review and approval of your project. If this form is not returned on time, your protocol may become inactive on the expiration date indicated in the continuing review notification letter.** Federal regulations and university policy prohibit continuation of research activity on inactive protocols. Therefore, enrollment of new subjects cannot occur on this project if it becomes inactive. In addition, research intervention or interaction with already enrolled subjects must stop if this project becomes inactive unless the IRB determines that it is in the best interest of individual subjects to continue.If your protocol becomes inactive, an electronic submission for new IRB Review may be required.

**Financial Conflict of Interest Disclosure**

[**Investigator Financial & Other Personal Interests Disclosure Form**](https://orra.rutgers.edu/coi) **for each investigator and key study personnel is required.**  Please the Rutgers Conflict of Interest website for more information at https://research.rutgers.edu/researcher-support/research-compliance/conflict-interest.

**Completion of Projects/How to Close Protocols**

When you have completed data analysis for your project, you can complete this form, under section B1 and the email the IRB with the specific language below.

**Student Investigators**: When your thesis or dissertation has been successfully defended (i.e., your committee does not require any data to be re-analyzed and all research-related activities have been completed), then you can complete the last option under Section B with your faculty advisor’s signature and your signature on the last page.

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**A. Funding Information:**

 **If there is no more funding, please indicate “No Longer Funded” below. If funding was not obtained, please indicate so with “N/A” below.** If this project is funded, or you are seeking such funding, complete the following *(attach additional sheets if applying to multiple funding agencies)*:

 \_\_\_ **New funding**. (Check here if this funding has been awarded after the previous IRB approval).

**Funding agency**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Contract or grant number**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PI of project**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Title of project**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Duration of grant**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**B. Current Status of the Research:**

**B1.** To indicate the status of your research, please check all that apply**:**

 \_\_\_ **Awaiting funding**. (Attach consent form\* & attach Recruitment materials)

 \_\_\_ **Anticipate enrolling new subjects**. (Attach consent form\* & attach recruitment materials)

 \_\_\_ **Follow up on previously enrolled subject**s.

 \_\_\_ **Analyzing data**.

 \_\_\_ **Completed data analysis. Project completed. No further action required. Proceed to Section G for signature.**

\_\_\_ Student Investigators only: **Completed all data analysis. Successfully defended a dissertation or a thesis\*\*. Project is complete. No further action required. Proceed to Section G for signature including advisor’s signature. \*\***If you haven’t defended yet, then please select analyzing data. The study can only be closed when the dissertation (or the thesis) has been successfully defended.

\* Consent form required. If you are making any changes to the consent form, then follow the instructions in Section E. If you are not making changes, please submit unmarked, unstamped copies of the current consent form and contact documents, (if any). **Be ensure that the consent form is on the current Rutgers IRB consent template version with all required information.**

**B2**. **TOTAL Number of subjects accrued:**

**A TOTAL of \_\_\_\_\_\_ subjects have been accrued** **since the beginning of the research.**(Cumulative number of subjects accrued for all years of the protocol; therefore, do NOT only indicate subject accrued in the past year or only subject’s whose data has been used for the research. All subjects who consented must be indicated above).

**C. New Research Findings:**

  **Federal policy requires that you provide the following information regarding any new research findings (yours or others) that could affect the risk to subjects and/or their willingness to participate in your study.**

**C1**. Summarize on a separate sheet any new information that is relevant to the risk to subjects or that may affect the subjects willingness to participate in the research (e.g., information or adverse effects resulting from this or other research, recent literature, reports on multi-center trials, and any other relevant information). \_\_\_ Attached \_\_\_ No new information

**C2.** Should any of this information be disclosed to subjects who have already participated in the study?

\_\_\_ Yes \_\_\_ No \_\_\_No new information

If yes, please describe on a separate page and attach to this form.

**C3.** Have any subjects experienced reportable unexpected reactions and/or adverse events or complications since last scheduled annual review?

\_\_\_ Yes \_\_\_ No If yes, please attach an Unexpected/Adverse Event Report\* or provide the date on which an Unexpected/Adverse Event Report\* was filed.

**C4.** Have any subjects complained about any aspects of their participation in the research?

\_\_\_ Yes \_\_\_ No If yes, please attach an Unexpected/Adverse Event Report\* or provide the date on which an Unexpected/Adverse Event Report\* was filed

**C5.** Please review your last-approved Informed Consent Form. Considering your experience in the conduct of this study, are the actual risks and benefits still adequately addressed in the informed consent form?

 \_\_\_ Yes \_\_\_ No

If no, please describe on a separate page and attach to this form.

**C6.** Has there been any difficulty obtaining/retaining subjects or obtaining informed consent during the previous approval period? \_\_\_ Yes \_\_\_ No

If yes, describe on a separate page and attach to this form.

**C7.** Please complete the following:

\_\_\_\_ Approximately how many potential subjects have refused participation? (If available)

\_\_\_\_ How many subjects have voluntarily withdrawn participation at their own initiative?

\_\_\_\_ How many subjects have withdrawn participation at the initiative of the PI?

 \* Unexpected/Adverse Event Report, found at: <https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-toolkit> under Paper Forms.

**D.** **International Research:**

 D1. Does your research involve international site(s)?

 \_\_\_Yes \_\_\_If no, proceed to section E. Amendments

D2. List all foreign countries where the approved work has been conducted:

D3. Are you still recruiting subjects and/or following subjects from these sites?

 \_\_\_Yes \_\_\_No

Note: If you plan on conducting work in ***additional foreign countries*** not already approved by the IRB, then please submit an amendment for the additional of any foreign countries where the research will occur (see section E below and attach Appendix C, International Appendix).

**Amendments**

**E.** Are you requesting any amendments to the last approved protocol, informed consent form(s), key personnel, and/or study documents (e.g., advertisements, surveys, questionnaires)?

\_\_\_ Yes \_\_\_ No

***Note: Changes in Key Personnel should be included as an amendment to this Continuing Review.***

If yes**,** address the following points on a separate sheet:

* **Amendments requested and reasons.**  If applicable, please provide two versions of all updated research procedures and any revised documents (e.g., protocol, surveys, questionnaires, etc.). Underline and use **boldface** type for additions and strike out for deletions on one copy. Provide one unmarked copy. (Unmarked means no revision marks or highlighting).
* **Effects of the requested amendments on risks, benefits and consent procedures.** (If the IRB determines that these changes are substantial, you may be asked to submit a new Request for IRB Review application.)

**If amendments pertain to the consent form, then please provide the following TWO versions of the new consent form(s): 1) a marked copy indicated any changes, and 2) a clean copy that will be stamped approved for use upon new IRB approval.**

**F. Key personnel**

Key personnel are defined as all individuals who are responsible for the design or conduct of the study.

**F1.** Date on which the principal investigator completed the CITI Training Program: \_\_\_\_\_\_\_\_

**F2.** List **all** key personnel for this protocol for the upcoming approval period.

New personnel to the project (since the last approval period) should be indicated with an asterisk\* after their name. Complete the following for each individual. Attach additional sheets if necessary.

Name: Phone:

Title: Fax:

Department: Email:

Mailing Address: Date of completion of CITI:

Name: Phone:

Title: Fax:

Department: Email:

Mailing Address: Date of completion of CITI:

**F3.** Have any key personnel **left** the research team since your last approval?

\_\_\_Yes \_\_\_No If yes, please identify names below.

1. [KP]
2. [KP]
3. [KP]
4. [KP]
5. [KP]

***Submission Checklist: Please include the items below where applicable:***

* + ***Appendix C International FullBoard/Expedited Studies Involving International Research***
	+ ***Additional funding information as requested under Section A.***
	+ ***Summaries of new research findings as requested under section C***
	+ ***Adverse Events form under Section C3 or C4.***
	+ ***Informed consent forms and any recruitment materials as requested under section B1, C5, or E.***
	+ ***Explanation of subject recruitment/maintenance issues*.**
	+ ***Amendment requests and revised documents as requested under Section E.***
	+ ***Additional Key Personnel information as requested under Section F.***

**G. Investigator’s Assurance:**

The information given in response to the questions above is accurate. I assure the Rutgers University Institutional Review Board for the Protection of Human Subjects that the use of human subjects has been conducted in accordance with the previously approved protocol and conditions. This area must include either a “wet” signature or an e-signature (not a typed name).

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 Principal Investigator Signature Date

 **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Faculty Sponsor Signature (if PI is a graduate student) Date

 **Print Name of Faculty Advisor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**Submission Instructions:**

**Please email this completed continuing review form** along with **all relevant materials** to IRBOffice@research.rutgers.edu.

Format:

* No ZIP Files
* Add your Title and Protocol Number to the E-mail Subject [if Available] and on the attachments
* **Do NOT Send a Hardcop**y of an E-mailed Submission