

Request for Amendment to an Approved IRB Protocol Application

Instructions: Only complete this form if you are requesting amendments/revisions to an active IRB project (even if the project was initially approved via administrative/limited (exempt) review).

The IRB must approve the requested revisions before implementing the changes.

Attach all relevant documents to the project in IRBNet that are directly affected by the requested change. Please submit as follows to IRBNet: (1) (updated) IRB Application, (2) (updated) Informed Consent(s), (3) (updated) Appendices, and (4) Amendment Application (this form)

An amendment may increase the risk level of the project, which may prompt the IRB to change the category of review for the project from a lower risk to a greater risk.

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| Principal Investigator (Current): | | |
| CITI Member ID Number: | | |
| Email: | | |
| Approved Protocol Number: | | |
| Approved Project Title | | |
| Select the proposed change(s) to the project (Type "x" in all that apply): | | |
| <input type="checkbox"/> Extension of project dates | <input type="checkbox"/> Project title | <input type="checkbox"/> Data source |
| <input type="checkbox"/> Assessments (i.e. survey/interview questions, activities or interventions) | <input type="checkbox"/> PI change* | <input type="checkbox"/> Personnel (other than PI)* |
| | <input type="checkbox"/> Research location | <input type="checkbox"/> Participant compensation |
| | <input type="checkbox"/> Advertisements/Flyers | <input type="checkbox"/> Other |
| Describe, in detail, the requested changes. If requesting more than one change, numerically list the changes (Use as much space as necessary). | | |
| *If adding research personnel, please include their name, CITI Member ID Number, and email for each individual listed: | | |
| | | |
| Select all documents that require revision or any documents submitted as a result of the requested change (Please attach any new/revised documents selected below to the submission via IRBNet) (Type "x" in all that apply): | | |
| <input type="checkbox"/> IRB Application | <input type="checkbox"/> Survey/Interview Questions | |
| <input type="checkbox"/> Permission Letter(s) | <input type="checkbox"/> Recruitment material (flyers, scripts, letters, etc.) | |
| <input type="checkbox"/> Consent Form(s) | <input type="checkbox"/> Other (Explain): | |
| Will the requested changes affect the risks or benefits of the project (Type "x" in all that apply)? | | |
| <input type="checkbox"/> No | | |
| <input type="checkbox"/> Yes (Explain): | | |