**The Catholic University of America**



 **Institutional Review Board for the Protection Of Human Subjects**

**Request to Amend an Approved Protocol**

**Please complete this form and return it to:** **Office of Sponsored Research** ***(Send the original and one copy).***

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| ***Principal Investigator’s Name Date*** |  | ***Date*** |

 ***Title of Study***

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***Protocol Number Original Approval Date Current Expiration Date***

**THE FOLLOWING ITEMS ARE REQUIRED FOR APPROVAL**

*(If the research covered by this renewal is limited to data analysis, please answer questions 1 and 4 only.)*

1. Number of subjects accrued:
2. Additional anticipated number of subjects for period covered by this renewal:

Please attach the following:

1. A copy of the current consent form clearly marked as “current”**.**
2. A summary of progress to date, including findings.
3. For research with more than minimal risk or research that provides and evaluates behavioral or psychological interventions, a summary of recent literature related to the research topic. (Federal policy requires that investigators inform subjects of important new information that might affect their willingness to participate in the research. This information may be findings of this research or of that carried out by others.)
4. A description of any adverse events or unanticipated problems involving risks to subjects and proposed solutions, any withdrawal of subjects from the research, or complaints about the research. Adverse events include required reporting of suspected child abuse to authorities.
5. A memo describing the requested changes.
6. A copy of a revised protocol with the changes from the approved protocol in bold-faced type.
7. A revised consent form incorporating all proposed changes.

**INVESTIGATOR'S CERTIFICATION**

Changes have been made to the protocol. I/we understand that we cannot use anything other than the approved

Protocol and procedures until receiving this approval with authorized IRB signature.

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***Signature of Principal Investigator and Faculty Advisor (if applicable) Date***

***Approved by:***

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 ***IRB Chair/ Expedited Reviewer/Human Protections Administrator (Circle One) Date***