



Georgetown University Institutional Review Board
Continuing Review Form (C-2)

(Please type form)

Principal Investigator	
Title of Project	

1. What is the status of your research project?

- Active (still enrolling subjects).
- Closed to subject enrollment, but subjects still on protocol regimen
- All subjects completed protocol regimen, but research open for data analysis and follow-up of subjects (EXPEDITED REVIEW)
- All research related activities completed including all data analysis and paper writing; request termination of research with IRB.
- Other _____

2. Subject Accrual Statistics:

Local Accrual Progress

	Total number of local subjects currently approved by the IRB
	Total number of subjects enrolled at the local site including those who are still being followed.
	Number of subjects enrolled at the local site since previous IRB review.
If the total number of subjects enrolled at the local site including those who are still being followed exceeds the number of subjects currently approved, please explain.	

National and International Accrual Progress

	Number of subjects enrolled nationally . <i>(if available and applicable)</i> .
	Number of subjects enrolled internationally . <i>(if available and applicable)</i> .
If the total number of subjects enrolled exceeds the number of subjects currently approved, please explain.	

Time Frame

	Estimated duration of total project (Please see "Duration of project" on original D-1 form)
Please justify keeping trial open if the duration of the study exceeds the duration listed in the original C-2 form that was approved by the IRB	



3. Withdrawals

	Participant withdrawals
	Withdrawals by PI

4. Have there been any complaints about the research since the last review? Reportable complaints are those that cannot be resolved by research staff

- Yes. If yes, please explain briefly
- No.

5. Has the research protocol, informed consent document, or recruiting material been modified in any way since the previous IRB review?

- Yes. If yes, please attach additional information to explain the changes.
- No

If yes, have all modifications been approved by the IRB?

- Yes
- No. If no, briefly explain, and attach additional information.

6. Adverse Events: Please attach a list of all study-related **adverse events**. You may use the “Canned Report” from the online CAER system titled “Display all AEs by Protocol #”

Please check one of the following three choices and submit additional information when designated:

- No adverse events have occurred since the previous IRB review.
- Adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and/or any investigator brochure.
- Yes there have been **unexpected adverse events** since the previous IRB review. **Please attach a summary of these adverse events; reports from other central monitoring entity will suffice. Please include any changes to the protocol or informed consent documents due to unexpected adverse events, including the date of IRB review or approval of the changes.***

Please check one of the following two choices and submit additional information when designated:

- There have been no **unanticipated problems** involving risks to subjects or others since the previous annual review.
- Yes there have been unanticipated problems since the previous annual review. Please attach a description of any local unanticipated problems involving risks to subjects or others.

7. Review research files for subjects on the study for the following:

Yes _____ No _____ Are there signed consent forms on all subjects?

Yes _____ No _____ Have terms of the protocol been followed?

Yes _____ No _____ Have there been any protocol deviations?

If there were deviations, were they reviewed and approved by the IRB?

Yes _____ No _____ If no, please attach an explanation.



8. Do any study investigators have a conflict of interest as defined in the Georgetown University Faculty handbook (<http://www.georgetown.edu/facultysenate/handbook.html#financial>) or MedStar Research Institute policy?

Yes _____ No _____ If yes, please attach an explanation.

Each “investigator” must submit a Georgetown University Study Specific Disclosure Form as part of this protocol application. “Investigator” includes the principal investigator and any other person who is responsible for the design, conduct, or reporting of research.

The Georgetown University Study Specific Disclosure Form is available for downloading from the IRB website: <http://ora.georgetown.edu/irb/irbDisclosure.htm>

Questions about the Georgetown University Study Specific Disclosure Form can be directed to the Office of Regulatory Affairs, Conflicts Regulation Office at 202-784-5313 or conflictsregulation@georgetown.edu

Guidance for Conflicts Disclosure in Publications and Presentations

Financial and/or Intellectual property interests (e.g. patents or patent applications) must also be disclosed in all related press releases, publications and presentations.

9. Attach copies of:

- Recent literature; published findings obtained thus far, including study-wide reports if applicable; or other relevant information (especially information about risks associated with the research) available since the last IRB annual review.
- Current IRB-approved informed consent document used for this study even if unchanged since the last IRB review
- Copy of most recent IRB Application (Protocol for Clinical Study, Form AB-1 or D-1) even if unchanged since the last IRB review
- Copy of adverse events and summaries, local and global (*see question 4*)
- Copy of data and safety monitoring reports since the last IRB approval (*if applicable*)
- For PI and any Co-Investigators: Proof of Human Research Protection Training and Study Specific Disclosure Form(s).
- Copy of current grant application (*if this research is sponsored by a federal agency*)



I certify that the above information accurately represents the status of the research and the subjects enrolled.

<p>_____</p> <p>Printed/Typed Name of Principal Investigator</p> <p>_____</p> <p>Signature of Principal Investigator</p>	<p>_____</p> <p>Date</p>
<p>_____</p> <p>Printed/Typed Name of Person Completing Form</p> <p>_____</p> <p>Signature of Person Completing Form</p>	<p>_____</p> <p>Date</p>
<p>_____</p> <p>Printed/Typed Name</p> <p>_____</p> <p>Signature of Department Chair (If the department chair has changed since the last review)</p>	<p>_____</p> <p>Date</p>