Cary Institute of Ecosystem Studies

CARY INSTITUTE OF ECOSYSTEM STUDIES
INSTITUTIONAL REVIEW BOARD (IRB)
Human Subjects Protocol Continuing Review Form

Instructions: Please use this form to submit a human subject protocol annual renewal request (for protocols subject to continuing review). This request can include proposed amendments.

Date:	**IRB Protocol #:**
Principal Investigator:	
Project Title:	
Protocol Approval Date:	**Protocol End Date:**
E-mail:	

Please answer the following questions regarding the listed protocol and return this form to Amanda Johnson in the Grants Office or e-mail it to grants@caryinstitute.org.

1) Would you like to renew the above named protocol?

☐ Yes

If yes, proceed to the next question.

☐ No

If no, see Investigator Assurance and sign. Your protocol will not be renewed.

2) Please provide the below information:
   a) Number of subjects enlisted in this protocol: _____
   b) A summary of any recent literature, findings, or other relevant information, especially information about risks associated with the research (if available and applicable).

   c) A copy of the current informed consent document, if different from the originally approved document and/or if changes were made or are being requested.

3) During this renewal, do you want to **amend** the above named protocol?

☐ Yes

If yes, please provide a description of the proposed changes on Cary letterhead. For example, describe any changes in the original approved protocol/methodology that relates to the research conducted and/or human subjects utilized in your research. If you are proposing changes in personnel, please provide documentation for the completion of appropriate training in research studies involving human subjects.

☐ No

4) Is the amendment request due to unanticipated effects that relate to the research conducted and/or human subjects utilized in your research that need to be addressed? Have there been any complaints about the research? If so, in your attached statement, please describe the issues and how you plan to ameliorate them.

☐ Yes

☐ No

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Investigator(s) Assurance:

The information and answers to the questions above are true and accurate to the best of my knowledge. I understand that prior IRB approval is required before initiating any changes that may affect the human subject participant(s) in the originally approved research protocol. I also understand that in accordance with federal regulations I am to report to the IRB or administrative designee any adverse events that may arise during the course of this research.

_____ ____/____/____

Signature of Principal Investigator Date

_____ ____/____/____

Approving Signature of IRB Chair Date

Approval of listed protocol/methodology is granted from ____/____/____ to ____/____/____