Annual Continuation Request Form

1. SUBMISSION INFORMATION	
1. IRB Number:	
2. Date of Expiration of Existing IRB Approval:	
3. Review Type:	☐ Expedited ☐ Full-Board

2. GENERAL STUDY INFORMATION		
1. Study Title:		
2. Principal Investigator:		Email:
3. Study Coordinator:		Email:

3. DETAILS PERTAINING TO THE CURRENT CONTINUTATION REQUEST	
1. Please provide a brief progress report to the originally approved proposal.	
2. Is the project being carried out as described in the original submission to ESISBA-IRB?	☐YES ☐NO If NO, please explain/describe the discrepancies:
3. Have any of the research subjects suffered any serious or unexpected harm, toxicities or side effects?	☐YES ☐NO If YES, please describe:
4. Have there been any internal or external audit of the research, preliminary (stopping rule) analyses, reports of data and safety monitoring boards, etc.?	☐YES ☐NO If YES, please describe:

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5. Has there been any significant change in the information on which the ESISBA-IRB provided ethical approval? **e.g. new knowledge from the literature, from the present project or from other related sources?**	☐YES ☐NO If YES, please describe the new information and indicate how it differs from that in the previous or original ethics approval, and its impact on the ethics of the research underway:
6. Have any amendments been made to the research protocol since the original approval?	☐YES ☐NO If YES, please explain: Were these amendments approved by the ESISBA-IRB? ☐YES ☐NO If YES, when: If NO, please provide reasons why: ***IMPORTANT: If the project, protocol and/or the previously approved consent form have changed since the original submission was approved, or if you are requesting amendments at this time – please provide the current or proposed versions of the research protocol and accompanying documents (e.g. informed consent) and indicate/highlight where the changes were made.***
7. Are you requesting any amendment(s) to the original application?	☐YES ☐NO If YES, please list and justify the proposed amendments. ***IMPORTANT: If the project, protocol and/or the previously approved consent form have changed since the original submission was approved, or if you are requesting amendments at this time – please provide the current or proposed versions of the research protocol and accompanying documents (e.g. informed consent) and indicate/highlight where the changes were made.***
8. When do you expect (month/ year) the project to be completed?	

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4. SIGNATURE	
Principal Investigator	Date: