Lafayette Institutional Review Board: Continuing Review Form

Default Question Block

Q1.
Continuing review is **not** required for:

- IRB-determined Exempt Review research
- IRB-determined Expedited Review research
- Research (regardless of review type) that has completed all interventions and now only includes analyzing data
- Research (regardless of review type) that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures.

If your study does not meet any of these conditions, it is subject to continuing review **annually**.

If Lafayette IRB conducted a full or expedited review of **and** approved your study prior to January 21, 2019, it is subject to annual continuing review until otherwise determined by Lafayette IRB. Thus, you must still submit a continuing review form before your IRB approval expires.

This form should ONLY be used to apply for continuing review of a study that was previously approved by the Lafayette College IRB and that involves no proposed changes to the original IRB-approved research protocol and procedures.

Q2.
Project title:

Q3.
Original IRB proposal number (this can be found on your IRB decision letter):

Q4.
Lafayette IRB Action Letter(s). Please upload the original IRB Action Letter here. Upload, as applicable, previous IRB renewal or change of protocol approval letter(s) in the fields that follow. You may also upload all letters as a single file. (Please upload as a pdf file)

Q5. **Additional Lafayette IRB action letters (as applicable)** (please upload as a pdf file)

Q6. **Additional Lafayette IRB action letters (as applicable)** (please upload as a pdf file)

Q7. **Additional Lafayette IRB action letters (as applicable)** (please upload as a pdf file)

Q8.
Study period for which IRB approval was originally received

Q9. **Was this protocol reviewed and approved by Lafayette IRB prior to January 21, 2019?**

- Yes
- No

Q10.
Current date:

Q11.
Principal Investigator's Contact Information:

First Name	
Last Name	
Department	
Address	
Email Address	
Phone Number	

Q12.
Renewal requested by:

- Faculty
- Student (note: students will need to submit a letter of support from their advisor for continuing review)
- Staff

Q13.
Upload your letter of support from your faculty advisor (please upload as a pdf file)

Q14.
Please provide a brief project summary and progress report:

Q15. **Upload a copy of your most recently IRB-approved informed consent document(s) (please upload as a Word document file)**

Q16.
Request for Project Renewal

I request a renewal of this project, for which (check all that apply)

- I am still collecting data
- I will continue to follow the previously IRB-approved protocol
- There are no changes to the IRB-approved research project (Note: If there are changes to the study, please submit via the Change of Protocol Submission Form)
- There have been no project-related risks or concerns thus far that require additional IRB review

Q17.
Please summarize any unanticipated problems or adverse events with the research that have occurred since IRB-approval

Q18.
Number of Subjects Enrolled:

Q19. **Is the number of subjects enrolled markedly different from the expected enrollment as described in your original IRB-approved protocol?**

- Yes
- No

Q20.
You answered that the number of subjects enrolled is markedly different from the expected enrollment as described in your original IRB-approved protocol. Please explain.

Q21. **Have any subjects discontinued participation in/withdrawn from the study?**

- Yes
- No

Q22.
Please provide the number of subjects who have discontinued participation in/withdrawn from the study. Also provide a summary of the reasons for withdrawal, if known.

Q23. **Have there been any complaints about the research from subjects since the last IRB review?**

- Yes
- No

Q24.

Please summarize any complaints about the research from subjects since the last IRB review.

Q25.

Electronic signature

As Principal Investigator, I recognize that while I await approval of this request, I may continue with the ongoing project (as long as the original approval has not expired and there have been no changes to the original IRB approved study) unless the risks to my participants are greater than originally anticipated. If the latter, I will stop data collection until the continuing review is complete. By typing my name below, I certify the veracity of this statement and of the contents of and attachments to this document.

Type Name