For IRB Office use only:

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| --- | --- | --- | --- |
| Date Received: date rec’d | Sent to Review: date rev’d | | Date Approved: date approved |
| Revision No. Rev no. | Version Date Code: date code | | |
| Original Review Method: Initial Review Method | | Continuation Review Method: CR Method | |
| NEW EXPIRATION DATE: New Expiration Date | | | |

If your IRB protocol was given an approval expiration date, this *IRB Continuing Review Form* must be submitted to the IRB no later than four weeks before that approval expiration date. No research may be conducted past the expiration date unless the IRB has reviewed and renewed the study.

# INSTRUCTIONS: This is a Microsoft Word form. Please complete all fields and enter “N/A” to any field that does not apply to your protocol. Do not use this form as a Google Doc.

**1. Project Information**

|  |  |  |
| --- | --- | --- |
| Project Title: | Please enter the title of your protocol | |
| IRB Log #: Please enter the IRB Log # | |  |
| Original Approval Date: Original approv. date | | Expiration Date: Expiration date |

**2. Contact Information**

|  |  |
| --- | --- |
| Principal Investigator: Please enter name of PI | Email: PI email |
| Advisor (if applicable): Name of research advisor | Email: Advisor email |
| Department: Please enter the PI’s department | |
| Names of all co-Investigators: Please list all the co-investigators on the protocol | |

**3. PROJECT STATUS:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Total number of participants enrolled in your study to date: | | | # participants | |
| How many participants was your study approved to enroll? | | | # participants | |
| How many more participants do you intend to enroll in the future? | | | # participants | |
| How many have withdrawn or been asked to withdraw to date? | | | # participants | |
| Describe the reasons for withdrawal from the study, if known: | | | | |
| Please describe reasons for withdrawal, if known | | | | |
| Comments: | | | | |
| Please include any information that the IRB should know about the past approval period. | | | | |
| Have any unanticipated problems or adverse events occurred during the last approval period? | | | | |
|  | Yes | No | |  |
| If “Yes”, please describe: | | | | |
| Describe all unanticipated problems or adverse events. | | | | |

**4.** **Information Since the previous review**

|  |  |  |
| --- | --- | --- |
| Are you aware of any new relevant information, either through the study itself or through outside sources (e.g., journal articles, conferences, communication with colleagues), that may indicate a **possible increased risk** of social, psychological, or physical harm to participants in this study? | Yes | No |
|
| Have the potential risks/benefits of this research changed since the last review? | Yes | No |
| Have there been any changes in personnel (principal investigator,  co-investigators, faculty advisor, etc.) for this project? | Yes | No |
|
| Are all investigators current with their human subject research **CITI training**? | Yes | No |
| If **yes** was answered to any of the items above, please explain below: | | |
| Please explain | | |

**5. PROJECT SUMMARY**

Please provide a brief summary of the progress made in this project since the last review:

|  |
| --- |
| Please provide a brief project summary |

**6. ARE THERE ANY CHANGES PLANNED FOR THE PROJECT?** Yes  No

If yes, please provide a detailed description of any changes that are being proposed for the study and provide a brief justification. REMEMBER: All changes must be approved before they are initiated in the protocol.

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| Please describe any planned changes |

**7. REVISED DOCUMENTS**

The IRB must review all materials that have been changed or added since the last review or approved revision. (e.g. new solicitation email, revised survey questions, updated consent forms, etc.)

|  |  |  |
| --- | --- | --- |
| Are you submitting newly revised documents with this form? | Yes | No |

**8. Certification**

|  |
| --- |
| I certify that the information provided above entirely and accurately describes the research project. I agree not to make any changes to the protocol without first seeking IRB approval, except in the case of immediate harm to participants. I agree to conduct research in accordance with the approved protocol. I agree to immediately report any unanticipated problems or adverse events to the [Chairperson](http://sites.jcu.edu/research/pages/contacts/) of the Institutional Review Board and my Research Sponsor, if applicable, as soon as they are discovered. |

|  |
| --- |
| **I agree to the above Certification Statement** |
| **Name of Principal Investigator:** Please enter your full name |
| **Today’s Date:** Click or tap to enter today’s date |

Submit this completed form as an email attachment to [irb@jcu.edu](mailto:irb@jcu.edu). Please include any revised documents with your form. You will receive a confirmation email when your submission is received. Please contact the IRB Office ([irb@jcu.edu](mailto:irb@jcu.edu), 216-397-1527) with any questions.

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Review Notes:

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| IRB Review Notes |