|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| For IRB Office Use Only: | | | | | | | | |
| Date Rec’d: |  | | Sent to Review: | |  | | Date Approved: |  |
| Revision No. |  | | Version Date Code: | |  | | | |
| Original Review Method: | |  | | CR Method: | |  | | |
| 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 protocol.

**INSTRUCTIONS:** Please complete all fields and enter “N/A” to any field that does not apply to your protocol. Submit this completed form and any supporting documents via email to [IRB@jcu.edu](mailto:IRB@jcu.edu). You will receive a confirmation email when your submission is received. Please contact the IRB Office (IRB@jcu.edu, 216-397-1527) with any questions.

# PROTOCOL INFORMATION

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Project Title: |  | | | | | |
| IRB Log No.: |  | | Review Category: | |  | |
| Original Approval Date: | |  | | Expiration Date: | |  |

# PRINCIPAL INVESTIGATOR INFORMATION

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator: |  | Email: |  |
| Advisor (if applicable): |  | Email: |  |
| PI’s Department: |  | | |
| Names of all co-Investigators: |  | | |

# PROJECT STATUS

|  |  |
| --- | --- |
| Total number of participants enrolled in your study to date: |  |
| Total number of participants your study is approved to enroll: |  |
| How many more participants do you intend to enroll in the future? |  |
| How many have withdrawn or been asked to withdraw to date? |  |
| Describe the reasons for withdrawal from the study, if known: | |
|  | |
| Is there any additional information the IRB should know about the past approval period? | |
|  | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Have any unanticipated or adverse events occurred during the last approval period? | | | | | | |
|  | Yes: |  | No: |  |  |
| If “Yes,” please describe: | | | | | | |
|  | | | | | | |

# INFORMATION SINCE THE PREVIOUS REVIEW

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| Are you aware of any new relevant information, either from the study itself or from 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? |  |  |
| Have the potential risks or benefits of this research changed since the last review? |  |  |
| Have there been any changes in personnel (principal investigator, co-investigators, faculty advisor, etc.) for this project? |  |  |
| Have any investigators lapsed in their human subject research CITI training? |  |  |
| If yes was answered to any of the items above, please explain below: | | |
|  | | |

# PROJECT SUMMARY

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

|  |
| --- |
|  |

# ARE THERE ANY CHANGES PLANNED FOR THE PROJECT?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes: |  | No: |  |  |
| If yes, please provide a detailed description of any proposed changes and provide a brief justification. REMEMBER: All changes must be approved before they are initiated in the protocol. | | | | | | |
|  | | | | | | |

# REVISED DOCUMENTS

The IRB must review all proposed changes to documents associated with the approved protocol (e.g., new solicitation email, revised survey questions, updated consent forms, etc.)

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

# CERTIFICATION STATEMENT

# Please read the following statement and enter your initials below.

|  |
| --- |
| I certify that the information I have provided entirely and accurately describes the status and conduct of 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 continue conducting this 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 Advisor, if applicable, as soon as they are discovered. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Initials: |  | **I agree to the above Certification Statement** | | |
| Name of Principal Investigator: | | | |  |
| Today’s date: | | |  | |

|  |  |
| --- | --- |
| For IRB Office Use Only: | |
| Supporting Documents: |  |
| Review Notes: |  |