*Federal law requires that all nonexempt research (with more than minimal risk) projects approved by the IRB be monitored annually. Please complete this form and submit to* *irb@uwsp.edu**. If you have completed your project, please indicate below. Projects not updated by the project anniversary date will be closed administratively. All data collection must stop until you receive IRB approval to continue work beyond the original protocol approval period.*

***After January 21, 2019: The Federal Revised Common Rule requires the transition of protocols approved prior to January 21, 2019 be transitioned to the new rule. Please complete the information below. Research continuing beyond the expiration date will be transitioned to the new rule and must complete a new protocol form. Additional documentation (consent forms, surveys, etc. should also be attached).***

Principal Investigator:

Co-PI (if applicable):

Protocol Number:

Project Title:

Protocol Approval Date:       Protocol Expiration Date:

Please check one of the following below:

[ ]  Study was never conducted. Please close the file.

[ ]  Study is completed. Data analysis is complete or limited to non-identifiable information. Please close the file.

[ ]  Study has been closed to enrollment of participants and all research interventions have been completed. Request a one (1) year extension for [ ]  long term follow up of participants OR [ ]  data analysis of identifiable information. **(Complete/transfer information to new application.)**

[ ]  Study is still in operation. Request a one (1) year extension for this project with no revisions to the approved protocol. **(Complete/transfer information to new application.)**

[ ]  Study is still in operation. Request a one (1) year extension and modification for this project. **(Complete/transfer information to new application.)**

**Study Summary**

1. How many participants have been enrolled in the study to date?
2. How many participants were indicated in the original intended sample size?
3. Were there any complaints by participants? If Yes, explain.
4. Were there any adverse or unanticipated events? If Yes, explain.

*(****NOTE:*** *All complaints and unanticipated events must be reported to the IRB within 72 hours)*

1. Where are the data stored?

**Extension Request**

1. Please provide a narrative summary of the study progress to date. Provide updated protocol documentation (Ex: protocol, consent documentation, surveys, etc)

1. Have any new or additional risks to participants been identified since the last IRB review? If Yes, explain.

**Modification Request**

Select the categories below if you wish to make changes to your protocol and attach all updated documents.

***NOTE:*** *Minor changes may be reviewed administratively. Significant changes to the project may be reviewed by the committee, as designated by the Chair.*

[ ]  Change in Study Title

[ ]  Change in Principal Investigator or Co-PI (For additional research personnel, submit a Personnel Addition Form)

[ ]  Change to research design, methods or procedures

[ ]  Change in research site(s)

[ ]  Addition or change to research population

[ ]  Change in recruitment

[ ]  Modification of deception

[ ]  Change to benefits, incentives or compensation to participants

[ ]  Addition or change in risks to participants

[ ]  Modification of Informed Consent/Assent

[ ]  Modification to identifiers collected in the study that would impact privacy and confidentiality of participants

[ ]  Change in research instruments (Ex: surveys, questionnaires, etc)

1. Describe the requested changes. Address all of the changes in an updated protocol and submit additionally.

1. Justify the reason for your change request(s).

1. How will the proposed changes impact the risks or benefits to research participants?

[ ]  I agree to conduct this study in accordance with federal IRB regulations and applicable institutional policies. I will not implement the aforementioned changes until IRB approval is granted.

Electronic signatures are acceptable when submitted to irb@uwsp.edu from a UWSP email account.

|  |  |
| --- | --- |
| Principal Investigator Signature |  Date |

|  |  |
| --- | --- |
| Faculty Advisor Signature (If applicable) |  Date |

**IRB Use Only Below This Line**

Status: [ ]  Closed [ ]  Extension Requested [ ]  Modification Requested

Original Protocol Review Category: [ ]  Exempt [ ]  Expedited [ ]  Full Board

New Review Category: [ ]  Exempt [ ]  Expedited [ ]  Full Board

Date:

Comments: