**DO NOT DELETE OR ALTER ANY PART OF THIS FORM**

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| **HRPP USE ONLY** | |
| **IRB #:** |  |
| **Rec. Log:** |  |

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| **CONTINUING REVIEW/CLOSEOUT** |

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| **Principal Investigator:** | [REQUIRED FIELD] |
| **Study Title:** | [REQUIRED FIELD] |
| **IRB #:** |  |

**Instructions:**

* Do not leave questions/[REQUIRED FIELD] blank; write or check "**N/A**" if not applicable.
* Because most studies no longer have expiration dates, our office is now asking for a complete set of all protocol-related documents to ensure we have the most recent versions of all materials.
* Please complete this form **only** if your project **requires continuing review** and was given an expiration date. If your project does not require continuing review and only requires an annual check-in, please complete the “Annual Check in/Closeout” form.

**If your study is not in data analysis, please ensure the following supporting materials currently in use are complete and included in your submission:**

* **Application (the most recently approved version)**
* **Addenda**

*For index of all HRPP addenda, please click* [*here*](https://irb.wsu.edu/forms/)*.*

* **Recruitment materials**

*For guidance on recruitment materials, please click* [*here*](https://irb.wsu.edu/documents/2021/01/recruitment-and-advertising-guidance.pdf)*.*

* **Informed consent materials/permission/assent materials**

*For guidance on consent, please click* [*here*](https://irb.wsu.edu/documents/2022/03/informed-consent-guidance.pdf)*.*

* **Data collection materials** (e.g., surveys, questionnaires, interview scripts, tools, measures, etc.)
* **Letters of institutional support/approval**
* **Debriefing scripts**
* **Non-WSU CITI training course certificates (if applicable)**

*For guidance on CITI training requirements and registration, please click* [*here*](https://irb.wsu.edu/training/)*.*

**How to submit:**

* All submissions must be emailed to [irb@wsu.edu](mailto:irb@wsu.edu).
* Please have the subject line read as: **“Continuing Review/Closeout” request for IRB ##### “Title”.**
* Submissions **must** be sent from a WSU email account.
* Submissions should be sent by the **PI**. If someone other than the PI (e.g., a graduate student, post doc, co-PI, or staff) is submitting the application on behalf of PI, the PI **must** be copied as a recipient.
* When submitting, please submit all supporting material attachments as **PDF** or **Word** documents only.

**Do not submit:**

* **Documents with tracked changes or comments**
* Links (e.g., social media sites, etc.)
* Documents via cloud sharing platforms (e.g., SharePoint, Google Drive, etc.)
* Zip files

**Please note:**

* Applications are processed in the order in which they are received.
* Submissions that include an incomplete application or that are missing supporting materials **cannot** be sent out for review and may result in a delay in your data collection. In the case of this event, you will receive an “Addition Materials Request (AMR)” notice indicating the corrective action needed.

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| **SECTION 1. PROJECT STATUS** |

**Please check one of the following below.**

1. **I want to renew IRB approval for this study. Mark the appropriate box below.**

This research is still active. Complete Section 2 and skip Section 3.

The research has never been initiated but will be conducted according to the currently approved procedures. Complete Section 2 and skip Section 3.

1. **I do not want to renew IRB approval for this study. Mark the appropriate box below**

The research has never been initiated and will not be initiated. Complete Section 3 only.

The research was started but closed prior to completion. Complete Section 3 only.

The research has been transferred to another institution. Complete Section 3 only.

1. **The research has been completed according to the IRB approved procedures. Complete Section 3 only.**

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| **SECTION 2. RENEWING IRB APPROVAL** |

1. **Please indicate what best reflects the current status of your research from the options below:**

New participant recruitment is still in progress.

Enrollment closed, but participants are still undergoing study procedures.

Enrollment closed, participants have completed study procedures, but are still in follow-up.

The research involves pre-existing records or samples only, no interaction/intervention with participants.

Remaining study activity is limited to analysis only, no further contact with participants.

The research has never been initiated but will be conducted.

1. Please provide the reason(s) why the study has not yet been initiated: [REQUIRED FIELD]
2. **Provide a summary of your progress to date:** [REQUIRED FIELD]

***PLEASE NOTE:***

*If modifications are needed, please complete section 4 of this form to explain the proposed changes. The modification will be reviewed for approval with this renewal. Changes may not be implemented until you receive IRB approval of the continuing review with the proposed amendment changes included.*

1. **To your knowledge since the last protocol approval date, has there been any new information, either through the study itself or through outside sources (e.g. literature, journal articles, conferences, etc.) that may indicate an increased risk to subjects in this study, including social, physiological, or physical harm)?**

☐ No

☐ Yes

*If yes, please summarize or attach supporting documentation:* [REQUIRED FIELD]

1. **Adverse events or participant complaints related to study procedures have occurred since the last renewal:**

☐ No

☐ Yes, these have NOT been reported to the HRPP. **Please submit the HRPP Reporting Form detailing the event**.

☐ Yes, these have already been reported to the HRPP.

1. **Please complete the table below.** If you have multiple subject pools (e.g., parents and children) indicate how many total participants have been recruited for each separate group. Please complete section 4 of this form if you need to increase or decrease enrollment for the study.

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| **Participant Group:** | **# Enrolled since project started (participants who have consented into the study):** | **# Completed since project started (participants who have completed all study procedures):** | **# Withdrawn or dropped since project started (participants who have consented into the study but have quit or been removed by the researchers):** | **Current Total Requested on protocol (the total number of participants identified in section 5.1 of the non-exempt application):** |
| [REQUIRED FIELD] |  |  |  |  |
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| **For records research - Type of record accessed:** | **# Accessed:** | **Current Total Requested on protocol:** |
| [REQUIRED FIELD] |  |  |
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| **SECTION 3. CLOSEOUT REQUEST** |

1. **Please complete the table below. If you have multiple subject pools (e.g., parents and children) indicate how many total participants have been recruited for each separate group. Please complete section 4 of this form if you need to increase or decrease enrollment for the study.**

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| **Participant Group:** | **# Enrolled since project started (participants who have consented into the study):** | **# Completed since project started (participants who have completed all study procedures):** | **# Withdrawn or dropped since project started (participants who have consented into the study but have quit or been removed by the researchers):** | **\*Current Total Requested on protocol (the total number of participants identified in section 5.1 of the non-exempt application):** |
| [REQUIRED FIELD] |  |  |  |  |
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| **For records research - Type of record accessed:** | **# Accessed:** | **Current Total Requested on protocol:** |
| [REQUIRED FIELD] |  |  |
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**For questions 2 – 5, please mark the correct box regarding the status of your project.**

1. ☐ **The research has been completed according to the IRB approved procedures. I do not wish to renew IRB approval for this study.**
2. ☐ This study involved the collection, storage, or use of any human biological specimens
3. If yes,explain what will happen with the specimens at the close of this study: [REQUIRED FIELD]
4. ☐ I certify that the proposed research has been completed and there will not be any further contact with the participants, use of, or access to, individually identifiable information.
5. ☐ **The study was started but was closed prior to completion. I do not wish to renew IRB approval for this study.**
6. ☐ This study involved the collection, storage, or use of any human biological specimens
7. If yes,explain what will happen with the specimens at the close of this study: [REQUIRED FIELD]
8. ☐ I certify that the proposed research has been closed out and there will not be any further contact with the participants, use of, or access to individually identifiable information.
9. ☐ **The research has been transferred to another institution. I do not wish to renew WSU IRB approval for this study.**
10. Indicate which institution(s) the research will be transferred to: [REQUIRED FIELD]
11. Indicate what data will be transferred: [REQUIRED FIELD]
12. ☐ This study involved the collection, storage, or use of any human biological specimens
    * 1. If yes,explain what will happen with the specimens at the close of this study: [REQUIRED FIELD]
13. I have worked with my department to identify the steps required to transfer the study:

☐ No

☐ Yes

1. ☐ **The research has never been initiated and will not be initiated. Please provide the reason(s) why:** [REQUIRED FIELD]
   1. List any additional risks that have been identified since the most recent approval: [REQUIRED FIELD]

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| **SECTION 4: STUDY CHANGE REQUEST** |

**Complete this section ONLY if you wish to amend your approved procedures and continue the research.**

1. **Select all parts of the research application or supporting materials that have been changed or updated:**

Amendment to currently approved procedures on the application (e.g., changes to general information section, data collection methods section, confidentiality section, subject recruitment section, participant numbers, risk and benefits section etc.)

Amendment to Recruitment materials

Amendment to Addenda

Amendment to currently approved consent/Assent/Permission forms

Amendment to Debriefing forms

Amendment to Data collection tools

Amendment to Investigator brochure

Other (please specify): [REQUIRED FIELD]

1. **List and describe the proposed changes to each document or sections on the application:** [REQUIRED FIELD]
2. **State the reasons for the proposed changes (If the only change is to the number of participants requested and you already provided the justification in section 2, question 8, enter “NA”):** [REQUIRED FIELD]
3. **Select all potential risks to the participants as a result of this amendment:**

N/A

Invasion of privacy to the subject or family

Breach of confidentiality

Physical harm or discomfort

Psychological/emotional discomfort or distress

Psychological effect that is more than discomfort or distress

Social stigmatization

Economic (e.g., employment, insurability)

Legal

Any study related activity which subjects might consider sensitive, offensive, threatening, or degrading

Withholding standard care and procedures

Significant time or inconvenience

Other (please specify): [REQUIRED FIELD]

1. **Indicate the change in risk as a result of the amendment:**

N/A

Not greater than minimal risk

Greater than minimal risk but presenting the prospect of direct benefit to individual subjects.

Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition.

Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

1. **Describe how will you minimize or handle these potential risks to protect subjects' rights and welfare (e.g., compensation, counseling, etc.):** [REQUIRED FIELD]
2. **Is it possible that you will discover a subject's previously unknown physical or psychological condition (e.g., disease, depression, suicidal ideation, genetic predisposition, etc.) as a result of your revised procedures?**

No

Yes

***If yes, complete (a)***

1. Explain in detail what previously unknown physical or psychological condition you may discover as a result of your revised procedures and how you will handle these situations: [REQUIRED FIELD]
2. **Is there a change in benefits because of this amendment?**

No

Yes

***If yes, complete (a-c)***

1. Describe the expected benefits of this amendment to the individual subjects: [REQUIRED FIELD]

***PLEASE NOTE:***

*Compensation is not considered a benefit.*

1. Describe the expected benefits of this amendment to society: [REQUIRED FIELD]
2. Describe how the benefits of this amendment outweigh the increased risks to the participants: [REQUIRED FIELD]

**PI name:** [REQUIRED FIELD]

**Date:** [REQUIRED FIELD]

**PI Signature\*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***If submitting from the PI’s WSU email, signature is not needed.***

**Name (if not submitted by PI):** [REQUIRED FIELD]

**Date:** [REQUIRED FIELD]

**Signature\*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***If submitting from the PI’s WSU email, signature is not needed.***