WEST VIRGINIA DEPARTMENT OF EDUCATION INTERNAL REVIEW BOARD

Request for Research Study Review

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| Title of research project | | IRB No. | Click here to enter text. | |
| Click here to enter text. | | *(Assigned by IRB Secretary)* | | |
| Anticipated beginning date (xx/xx/xxxx) | | Anticipated ending date (xx/xx/xxxx) | | |
| Click here to enter a date. | | Click here to enter a date. | | |

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| Type of Review Requested To qualify for an *Exempt* or *Expedited* review, the study must pose no more than minimal risk to human subjects. Minimal risk is characterized as *the probability and magnitude of harm or discomfort in the research are not greater in and of themselves than those encountered in daily life.* | |
| Select which of the following types of review you are requesting: Choose an item. | |
| Review period requested | 6 months  12 months |

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| Sponsoring Organization If there is more than one sponsoring organization, provide this information for each one in an attachment | | |
| Sponsoring organization (e.g., U.S. Department of Education) | | Sponsor Contact Person |
| Click here to enter text. | | Click here to enter text. |
| Phone | Fax | Email |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |

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| Principal Investigator Involved in This Project A completed and signed Principal Research Investigator Information and Certification form must be attached to this Review Request. | |
| Name | Position/Organization |
| Click here to enter text. | Click here to enter text. |

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| Research Staff Involved in This Project For each of the staff listed below, a completed Co-Investigator Information and Certification form must be attached to this Review Request. | | |
| Name | Position/Organization | |
| Click here to enter text. | Click here to enter text. | |
| Name | Position/Organization | |
| Click here to enter text. | Click here to enter text. | |
| Name | Position/Organization | |
| Click here to enter text. | Click here to enter text. | |
| Name | Position/Organization | |
| Click here to enter text. | Click here to enter text. | |
| Is there an adequate number of qualified staff for this project? | | Choose an item. |
| Is there a process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions? | | Choose an item. |
| Is any special training required to do the data collection required in this study? | | Choose an item. |
| If yes, please describe training. | | |
| Click here to enter text. | | |
| Is this a multicenter study? | | Choose an item. |
| If yes, who will be the lead investigator of this study (WVDE or another?) | | Click here to enter text. |
| If this is a multicenter study, briefly describe the management and sharing among sites of information obtained in this research that may be relevant to the protection of research participants, such as   * Unanticipated problems involving risks to the participants, * Interim results, * Protocol modification, or * Handling confidential information about individuals. | | |
| Click here to enter text. | | |

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| Research Protocol | |
| What is the purpose of this study? | |
| Click here to enter text. | |
| What is the scientific or scholarly rationale? | |
| Click here to enter text. | |
| What research methods will you use? | |
| Click here to enter text. | |
| Please include a description of all the data to be collected. | |
| Click here to enter text. | |
| Will you use any survey or other measurement instruments? If yes, you must attach draft copies. | Choose an item. |
| What are the risks and potential benefits of the study? | |
| Click here to enter text. | |
| What criteria will you use for inclusion or exclusion of subjects in this study? | |
| Click here to enter text. | |

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| Study Subjects and Procedures Minimal risk means that *the probability and magnitude of harm or discomfort in the research are not greater in and of themselves than those encountered in daily life.* | | | | | | |
| Does the research present more than minimal risk? | | | | | | |
| Choose an item. | | | | | | |
| If yes, describe the provision for monitoring the data collected to ensure the safety of participants. | | | | | | |
| Click here to enter text. | | | | | | |
| Will external on-site data collection take place? | | Choose an item. | | | | |
| If yes, in an attachment, list external sites where the research will be conducted (e.g., schools, district central offices, community centers). For each site, indicate the following:   * The name of the site * Whether the site has granted permission for the research to be conducted (attach approval letters) * Contact information for the site * If the site has an IRB, indicate if the IRB approved the research or if they plan to defer to the WVDE IRB. | | | | | | |
| If on-site data collection is to be done, will you be on the premises whenever data are collected? | | | | | | |
| Choose an item. | | | | | | |
| If no, describe what supervision will be provided on site. | | | | | | |
| Click here to enter text. | | | | | | |
| If follow-up on-site data collection is to be done, will you be on the premises whenever it is done? | | | | | | |
| Choose an item. | | | | | | |
| If no, who will conduct the follow-up data collection? | | | | | | |
| Name and degree(s) | Position and Organization | | | | | |
| Click here to enter text. | Click here to enter text. | | | | | |
| Anticipated number of subjects | Total = Click here to enter text. | | Minimum = Click here to enter text. | | Maximum = Click here to enter text. | |
| Age of subjects | Minimum age = Click here to enter text. | | | Maximum age = Click here to enter text. | | |
| Gender of subjects | Choose an item. | | | | | |
| Does the study exclude pregnant women or women of childbearing age? | | | | | | Choose an item. |
| If yes, please identify the rationale. | | | | | | |
| Click here to enter text. | | | | | | |

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| Recruitment | | | | | | | |
| From what locale(s) will you draw your subjects? | | | | | | | |
| Click here to enter text. | | | | | | | |
| Explain how you will have access to a population that will allow recruitment of the required number of participants within the proposed recruitment period. | | | | | | | |
| Click here to enter text. | | | | | | | |
| Will recruitment involve the use of email or other media? | | | | Choose an item. | | | |
| If yes, the IRB must review any subject recruitment materials along with information on their placement and the type of targeted audience. Indicate which media will be used (check all that apply). | | | | | | | |
| Email | Web | Radio | Television | | Print | Letters | Other |
| If other, describe below. | | | | | | | |
| Click here to enter text. | | | | | | | |

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| Informed Consent | | | |
| Will the research require the subjects’ informed consent? | | Choose an item. | |
| If no, you must attach Request for Waiver of Informed Consent form. | | | |
| If yes,   * attach any form(s) you will use, or * if documentation of informed consent is not feasible, attach a Request for Waiver of Informed Consent form   Explain how you will obtain informed consent below. | | | |
| Click here to enter text. | | | |
| Will the principal investigator conduct the consent? | | Choose an item. | |
| If no, who will? What informed consent training has this individual received? | | | |
| Click here to enter text. | | | |
| What steps will be taken to minimize the possibility of coercion or undue influence? | | | |
| Click here to enter text. | | | |
| How long will the potential subject have to decide to take part in the study? | | Click here to enter text. | |
| How will you assess comprehension of informed consent? | | | |
| Click here to enter text. | | | |
| Will any of the subjects have primary languages other than English? | | | Choose an item. |
| If yes, is there an experienced translator available? | | | |
| Choose an item. | | | |
| What languages? | | | |
| Click here to enter text. | | | |
| Will the consent form be translated? | Choose an item. | | |
| If yes, into what languages? | | | |
| Click here to enter text. | | | |
| Will all subjects be legally competent? | Choose an item. | | |
| Will all subjects be mentally capable? | Choose an item. | | |
| Will any subjects be vulnerable to coercion or undue influence? | Choose an item. | | |
| What additional safeguards will be in place to protect any vulnerable subjects (i.e., children, pregnant women, prisoners, cognitively impaired or mentally disabled participants, economically or educationally disadvantaged, elderly, or non-English speaking)? Describe. | | | |
| Click here to enter text. | | | |

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| Confidentiality | | | |
| Where will the signed consent form(s) be filed? | | | |
| Click here to enter text. | | | |
| Will copies be made of the signed consent form(s)? | Choose an item. | | |
| If yes, where will the copies be filed? | | | |
| Click here to enter text. | | | |
| Who will have access to the research record(s) besides your research staff and the agencies already authorized access such as federal auditors and the study coordinator? | | Choose an item. | |
| If other, describe below | | | |
| Click here to enter text. | | | |
| Where will subjects’ records be stored during the study? | | | |
| Click here to enter text. | | | |
| Where will subjects’ records be stored after completion of the study? | | | |
| Click here to enter text. | | | |
| Are subjects’ forms coded to protect privacy? | | | Choose an item. |
| If yes, where is the key to the code stored? (Do not use the subject’s Social Security Number as an identifier.) | | | |
| Click here to enter text. | | | |
| Who has access to the code key? | | | |
| Click here to enter text. | | | |
| If no, what method of protecting identifiers will be used? Describe. | | | |
| Click here to enter text. | | | |
| What other provisions are included in the protocol to protect the privacy interests of participants? | | | |
| Click here to enter text. | | | |

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| Monetary Issues | |
| Are subjects paid for participation in the study? | Choose an item. |
| Are subjects reimbursed for expenses? | Choose an item. |

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| Certifications and Assurances | | |
| I am responsible for the conduct of this research protocol, including the co-investigator(s) and other research staff. I have certified that all co-investigator(s) and other research staff have completed the training requirements. | | |
| I hereby certify that   * The information contained in this document is accurate and correct. * I will carefully follow the approved research protocol and submit **all** changes to the IRB for consideration **before** incorporating them into the study. * I will notify the IRB of any deviations from the approved research protocol taken in an emergency to protect the subject from harm; and any unanticipated problem, or serious, unusual, or unanticipated adverse event. | | |
| I or my designee will abide by the informed consent process with each subject and document this process on the approved consent form, allowing each subject adequate time before the study to decide voluntarily to participate in this study.  I will protect the rights and welfare of each subject to the best of my ability. | | |
|  |  | Click here to enter a date. |
| Principal Investigator’s Signature |  | Date |

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| Attachments Checklist |
| Please attach the following documents, as appropriate, in the order listed.  For sponsored studies, a copy of the grant application or proposal.  For studies with multiple sponsoring organizations, a list with the following information  Name of organization  Name of sponsor contact person  Contact information, including phone and fax numbers and email address  Principal Investigator Information and Certification form  For studies with additional co-investigator(s), Co-Investigator Information and Certification form(s)  Survey or other measurement instruments that will be used in the study.  For studies with external data collection (e.g., at schools, district central offices, community centers), a list of the site(s) with the following information for each:  Name of the site  A statement indicating whether the site has granted permission for the research to be conducted  Contact information for the site  If the site has an IRB, a statement indicating if the IRB approved the research or if they plan to defer to the WVDE IRB.  For studies with external data collection site(s), approval letters from each site granting permission for research to be conducted.  For studies involving the recruitment of subjects, all recruitment materials (letters, email, radio copy, etc.)  For studies that collect data from human subjects, informed consent forms and any associated materials  For studies requesting a waiver of informed consent, Request for Waiver of Informed Consent form.  For studies requesting a waiver of documentation of informed consent Request for Waiver of Informed Consent form |