WEST VIRGINIA DEPARTMENT OF EDUCATION INTERNAL REVIEW BOARD

Modification Request Form

A modification request is necessary when an investigator wishes to implement a change to a previously approved project if that change constitutes a significant deviation from what was approved in the initial IRB Research Application and/or accompanying materials. Modifications may only be requested for projects that are currently in approval status. Furthermore, modifications may be either minor or major in scope. Investigators are referred to the WVDE IRB Manual for details regarding these definitions. For minor modifications, investigators may use this Modification Request Form. For all major modifications, principal investigators are required to resubmit the approved study protocol and materials, highlighting the proposed changes.

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| --- | --- |
| Title of research project | IRB No.  |
| Enter text. | Enter text. |
| Principal investigator | Date modification requested |
| Enter text. | Enter a date. |
| 1. Please describe the proposed modification(s) to the project. Use enough detail to inform the IRB reviewer of all changes to your project. You may include additional pages if necessary.
 |
| Enter text. |
| 1. Is/are the modification(s) being submitted in response to a previously reported adverse event?
 | [ ]  Yes [ ]  No  |
| * 1. If yes, has the adverse event been reported to the WVDE IRB per the instructions in the WVDE IRB Manual?
 | [ ]  Yes [ ]  No [ ]  N/A |
| 1. In your estimation, do any of the proposed changes associated with the modification(s) impact the level of risk associated with participation in the research project?
 | [ ]  Yes [ ]  No  |
| a. If yes, please explain. |
| Enter text. |
| 1. Are you proposing any additions/revisions of the research staff approved to work on this project as part of the modification(s)?
 | [ ]  Yes [ ]  No  |
| * 1. If yes, please include the necessary IRB Principal Investigator Information and Certification Form and/or IRB Co-Investigator Information and Certification Form as attachments.
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| 1. Are you proposing any **NEW** data collection activities as part of the modification(s)?
 | [ ]  Yes [ ]  No  |
| a. If yes, please attach* A copy of the proposed collection protocol and accompanying informed consent form (if applicable).
* A description of the population to be studied, any methodological details regarding sampling to be employed, and a description of the consent procedures to be utilized.
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| 1. Are you proposing **REVISIONS** to existing data collection activities as part of the modification(s)?
 | [ ]  Yes [ ]  No  |
| * 1. If yes, please attach your revised data collection protocol(s) and highlight the changes to be reviewed.
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| * 1. If you are changing other aspects of the activity (e.g., sampling methods, population being studied, or addition of research sites) please describe these changes in an attachment. Note that some changes, such as the addition of research sites, may require additional documentation. Investigators are encouraged to review the IRB Research Application requirements when making this determination.
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| 1. Are you proposing to revise a previously approved informed consent document to include information associated with the proposed modification(s)?
 | [ ]  Yes [ ]  No  |
| a. If yes, please attach your revised version and highlight the changes to be reviewed. |
| **Submitted by** |
|  | Enter a date. |
| Principal investigator’s signature |  | Date |
| Print, sign, and submit this form and attachments toIRB SecretaryWest Virginia Department of EducationBuilding 6, Room 7501900 Kanawha Boulevard, EastCharleston, WV 25305 |

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| **THIS SECTION FOR IRB USE ONLY** |
| 1. Is/are the proposed modification(s) substantial enough to warrant submission of a revised version of the study protocol?
 | [ ]  Yes [ ]  No  |
| 1. If yes, discontinue review of this form, contact the principal investigator, and request submission of a revised version of the study protocol highlighting the requested changes and including any additional required documentation.
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| 1. If no, please indicate approval status and sign below.
 | [ ]  Approved |
|  |
| IRB reviewer’s signature |  | Date |

 *Revised 05.15.2017*