WEST VIRGINIA DEPARTMENT OF EDUCATION INTERNAL REVIEW BOARD

Request for Waiver of Informed Consent

This form is submitted with the Research Application. It is not required for exempt studies.

Under special circumstances, investigators can request one of three types of waivers to obtaining written informed consent from research subjects.

1. *Waiver or alteration of the informed consent process—*With this waiver, the investigator may provide to the subject a consent that does not include or that alters one or all of the required elements. Examples include when a researcher is conducting secondary data analysis and the subjects cannot be located or when requiring informed consent might somehow actually have negative consequences for research subjects.
2. *Waiver of parental permission—*This waiver would be used in cases where something may be legal for a child to do without parental permission and obtaining parental permission would violate the child’s privacy. An example is surveying children (which would require parental permission) but the survey is about the child’s experience with an abortion or child abuse.
3. *Waiver of written documentation that informed consent was obtained*—With this waiver, the investigator would be required to read or provide the informed consent form to a subject, but would not need to obtain the subject’s signature on the consent form. Examples include some internet or phone surveys or when signing the form might have some negative consequence for the subject. It must be emphasized that these waivers will be given only when there are compelling reasons for doing so.

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| Title of research project | IRB No. |
| Click here to enter text. | Click here to enter text. |
| The Institutional Review Board determines which type of consent applies to your research, but please indicate the type that you are requesting. | |
| Waiver or alteration of the informed consent process. (Complete Section A)  Request for waiver of parental permission. (Complete Section B)  Waiver of written documentation that informed consent was obtained. (Complete Section C) | |

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| A. REQUEST FOR WAIVER OR ALTERATION OF THE INFORMED CONSENT PROCESS. I believe that this protocol is eligible for waiver or alteration of required elements of the informed consent process because the protocol meets all of the following criteria. (Provide protocol-specific supporting information for each criterion that justifies the findings for the following.) | |
| 1. The research presents no more than “minimal risk” of harm to subjects. | |
| Click here to enter text. | |
| 1. The waiver or alteration will not adversely affect the rights and welfare of the subjects | |
| Click here to enter text. | |
| 1. The research could not practicably be carried out without the waiver or alteration. | |
| Click here to enter text. | |
| 1. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. | |
| Click here to enter text. | |
| 1. Elements of informed consent for which a waiver or alteration is requested and the rationale for each: | |
| Click here to enter text. | |
| 1. The research does not involve non-viable neonates. | True |
| 1. The research is not subject to FDA regulation. | True |

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| B. REQUEST FOR WAIVER OF PARENTAL PERMISSION I believe that this protocol is eligible for waiver parental permission because the protocol meets all of the following criteria: (Provide protocol-specific supporting information for each criterion that justifies the findings for one of the following two options.) | |
| O P T I O N 1 | |
| 1. The research presents no more than “minimal risk” of harm to subjects. | |
| Click here to enter text. | |
| 1. The waiver or alteration will not adversely affect the rights and welfare of the subjects | |
| Click here to enter text. | |
| 1. The research could not practicably be carried out without the waiver or alteration. | |
| Click here to enter text. | |
| 1. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. | |
| Click here to enter text. | |
| 1. Elements of informed consent for which a waiver or alteration is requested and the rationale for each: | |
| Click here to enter text. | |
| 1. The research does not involve non-viable neonates. | True |
| 1. The research is not subject to FDA regulation. | True |
| O P T I O N 2 | |
| 1. The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children). | |
| Click here to enter text. | |
| 1. An appropriate mechanism for protecting the children who will participate as subjects in the research will be substituted. | |
| Click here to enter text. | |
| 1. The research is not subject to FDA regulation. | True |
| 1. The waiver is consistent with federal, state, and local law. | |
| Click here to enter text. | |

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| C. REQUEST FOR WAIVER OF WRITTEN DOCUMENTATION OF INFORMED CONSENT (This waiver is not required when the consent process is waived.)  I believe that this protocol is eligible for a waiver of written documentation of informed consent because the protocol meets one of the following criteria.  NOTE: Even when documentation of informed consent is waived, the investigator is required to give subjects full consent information, and to obtain their voluntary consent orally.  (Provide protocol-specific supporting information for each criterion that justifies the findings for one of the following two options.) | |
| O P T I O N 1 (Example: Conducting interviews with street gang members about illegal gang activities. The only record of the name or other identifying information of the subject would be the signed consent form and knowledge of an individual’s participation or information provided could lead to potential legal, social, or physical harm.) | |
| 1. The only record linking the subject and the research would be the consent document. | |
| Click here to enter text. | |
| 1. The principal risk would be potential harm resulting from breach of confidentiality. | |
| Click here to enter text. | |
| 1. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject’s wishes will govern. | |
| Click here to enter text. | |
| 1. The research is not subject to FDA regulation. | True |
| O P T I O N 2 (Example: Using an anonymous survey consent or conducting telephone interviews with political staffers about how recent fundraising rules have changed the campaign process and no questions are being asked that could result in potential embarrassment, personally or professionally.) | |
| 1. The research presents no more than minimal risk of harm to subjects. | |
| Click here to enter text. | |
| 1. The research involves no procedures for which written consent is normally required outside of the research context. | |
| Click here to enter text. | |

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| APPROVAL (IRB Chair or Designee: Check all that apply to indicate that the waiver or alteration is approved and to indicate agreement with the investigator’s protocol-specific findings justifying the waiver.) | |
| Waiver or alteration of the informed consent process  Request for waiver of parental permission  Waiver of written documentation that informed consent was obtained  NOTE: To approve a waiver of written documentation of informed consent the investigator must provide a written document describing the information to be disclosed. This document has to include all required and appropriate additional elements of consent disclosure, unless the consent process has been altered.  Choose one of the following when approving a waiver of written documentation:  The investigator must provide a written description of the information provided orally to the participant.  The investigator is not required to provide a written description of the information provided orally to the participant. | |
| Name of IRB Chair or Designee | Date Approved |
| Click here to enter text. | Click here to enter a date. |

This form was adapted from the Marshall University IRB Request for Waiver of Informed Consent Form. Revised 01.30.13