

Virginia Department of Health
Institutional Review Board
109 Governor Street, 7th Floor
P.O. Box 2448
Richmond, Virginia 23218-2448
VDHIRB@vdh.virginia.gov



Request for Waiver of Informed Consent Documentation or Informed Consent Waiver/Alteration

(To be submitted with the Request for Review of Research Involving Human Participants)

Under special circumstances, Principal Investigators can request one of two kinds of waivers to obtain written informed consent from research subjects. *These waivers will be given only when there are compelling reasons for doing so.*

1. The waiver of written documentation is where informed consent is obtained orally. The IRB may waive the requirement when the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality; that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or if the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
2. The waiver or alteration of informed consent may be approved by the IRB if the research involves no more than minimal risk to the subjects; the research could not practicably be carried out without the requested waiver or alteration; if the research involves using identifiable private information or identifiable biospecimens, the research could not be carried out practicably without using such information or biospecimens in an identifiable format; the waiver or alteration will not adversely affect the rights and welfare of the subjects; and whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Please check which type of consent waiver is being requested:

- Waiver of written documentation Waiver and alteration of informed consent

- If requesting a waiver of written documentation, briefly describe why this is necessary.

- Please answer each of the following questions regarding your request for a waiver or alteration of informed consent. Make sure that each response includes a thorough explanation. Please provide any supporting documentation as appropriate.
 1. Will the research in its entirety involve more than minimal risk to participants? Please identify the risk.
 2. Why is it impractical to conduct the research without the waiver/alteration?
 3. Will waiving/altering informed consent adversely affect subjects, their rights, or their welfare? Please explain.
 4. Will pertinent information be provided to the subjects later, if appropriate? If yes, when?
 5. Can the research be conducted practicably without access/use of the protected health information (PHI)?
 6. Are the privacy risks to individuals whose protected health information is to be used or disclosed reasonable relative to (a) the anticipated benefits to the individuals, if any, and (b) the importance of the knowledge that may reasonably be expected to result from the research?
 7. Is there an adequate plan to protect the identifiers from improper use and disclosure?

Briefly explain the plan.

8. Is there an adequate plan to destroy the identifiers at the earliest opportunity, consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Principal Investigator

I certify that the information I provided is correct and complete.

_____ Attestation of Principal Investigator

_____ Attestation of Faculty
(if applicable)

Signature of Principal Investigator

Date

Signature of Faculty Supervisor (if applicable)

Date

(If the principal investigator is a student, the faculty supervisor must also sign)

This form along with supporting documentation may be submitted electronically to vdhirb@vdh.virginia.gov or by mail to:

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