**Request for Waiver of Informed Consent**

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| --- |
| Title of Research Project: |
| Click here to enter text. |

|  |  |
| --- | --- |
| IRB Submission Number (Obtain from the VDSS IRB): | Submission Date: |
| Click here to enter text. | Click or tap to enter a date. |

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| --- |
| Primary Investigator(s): |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| PI Signature | Signature Date |
| Click here to enter text. | Click or tap to enter a date. |

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.*

The first is a waiver of written documentation. With this waiver, the investigator is required to read or provide the informed consent form to a participant but does not need to obtain the participant’s signature on the consent form. Examples when this waiver might be applicable include some Internet or telephone surveys or when signing the consent form might have negative consequences for the subject.

The second is a waiver of informed consent itself. With this waiver, the investigator is not required to give, or read, the informed consent form to a participant. This waiver may be approved by the IRB if the research meets specific federal regulation criteria.

**Please check which type of consent waiver is being requested:**

[ ] Waiver of written documentation(*complete the* [*Waiver of Written Documentation Request Section*](#_Waiver_of_Written) *below*)

[ ] Waiver/alteration of informed consent(*complete the* [*Waiver/Alteration of Informed Consent Request Section*](#_Waiver/Alteration_of_Informed)*below*)

# Waiver of Written Documentation Request Section

*In order for your Waiver of Written Documentation request to be considered, please answer fully each of the following questions in this section. Make sure that each response includes a thorough explanation and description. Please provide supporting documentation, as appropriate.*

1. **Would the informed consent form be the only record linking the subject in the research AND the principal risk to the subject would be potential harm resulting from a breach of confidentiality?** Refer to 46.117(c)(1)(i).

[ ]  Yes [ ]  No

1. If Yes, please explain.

Click or tap here to enter text.

**2. Does the research present no more than minimal risk of harm to subjects AND involve no procedures for which written consent is normally required outside of the research context?** Refer to 46.117(c)(1)(ii).

[ ]  Yes [ ] No

1. If Yes, please explain.

Click or tap here to enter text.

**3. Are the subjects (or legally authorized representatives) members of a distinct cultural group or community in which signing forms is not the norm AND the research presents no more than minimal risk of harm to subjects AND there is an appropriate alternative mechanism for documenting that informed consent was obtained?** Refer to 46.117(c)(1)(iii).

[ ]  Yes [ ] No

If Yes, please explain.

Click or tap here to enter text.

**End of Waiver of Written Documentation Request Section**

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

***Once all necessary questions are completed, email this form to:*** **irb@dss.virginia.gov****.**

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# Waiver/Alteration of Informed Consent Request Section

*In order for your Waiver/Alteration of Informed Consent request to be considered, please answer fully each of the following questions in this section. Make sure that each response includes a thorough explanation and description. Please provide supporting documentation, as appropriate.*

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| 1. **Are you requesting a waiver or alteration?**

**[ ]** Waiver **[ ]** AlterationIf Alteration, please explain.     Public Benefit and Service Programs Waiver/Alteration: 1. **Will the research or demonstration project be conducted by or subject to the approval of state or local government officials AND could not be practicably carried out without the waiver or alteration AND is designed to study, evaluate, or otherwise examine one of the following areas?** Refer to 46.116(e)(3)(i-ii).

[ ]  Public benefit or service programs; [ ]  Procedures for obtaining benefits or services under those programs; [ ]  Possible changes in or alternatives to those programs or procedures; or [ ]  Possible changes in methods or levels of payment for benefits or services under those programs |
|  |

[ ] Yes [ ] No

**If Yes, please select which area(s) above and explain.**

Click or tap here to enter text.

*If Yes, skip to* [End of *Waiver/Alteration of Informed Consent Request* Section*.*](#_End_of_Waiver/Alteration)

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| --- |
| 1. General Waiver Alteration:
2. **3. Will the research, in its entirety, involve more than minimal risk to participants?**

[ ] Yes [ ] No1. **Identify the risk.**

Click or tap here to enter text. |
| 1. **2. Could the research be conducted practicably without the requested waiver or alteration?**

[ ] Yes [ ] NoIf No, please explain.Click or tap here to enter text. |
| **3. Could the research be conducted practicably without access to and use of personally identifiable information or identifiable biospecimens?** [ ] Yes [ ] No1. If No, please explain.

Click or tap here to enter text.1. **4. Will waiving/altering informed consent adversely affect subjects, their rights, or their welfare?**

[ ] Yes [ ] No1. If No, please explain.

Click or tap here to enter text. |
| 1. **5. Will additional pertinent information be provided to the subjects (or their legally authorized representatives) later, if appropriate?**

[ ] Yes [ ] No1. If Yes, when?

Click or tap here to enter text. |

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| **6. Are the privacy risks to individuals whose 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?**[ ] Yes [ ] NoIf Yes, please explain.Click or tap here to enter text. |
| **7. Is there an adequate plan to protect personally identifiable information or identifiable biospecimens from improper use and disclosure? Please briefly explain the plan.** Click or tap here to enter text.**8. Is there an adequate plan to destroy any identifiers at the earliest opportunity, consistent with conduct of the research, unless there is a research justification for retaining the identifiers or such retention is otherwise required by law? Please briefly explain the plan.**Click or tap here to enter text. |

# End of Waiver/Alteration of Informed Consent Request Section

***Once all necessary questions are completed, email this form to:*** **irb@dss.virginia.gov****.**